

Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR)



A dissertation submitted in partial fulfilment of the rules and regulations for MD General Medicine examination of the Tamil Nadu Dr.M.G.R Medical University, Chennai, to be held in May, 2018

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DECLARATION

This is to declare that this dissertation titled —“Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR)” is my original work done in partial fulfilment of rules and regulations for the MD General Medicine examination of the Tamil Nadu Dr.M.G.R Medical University, Chennai to be held in May, 2018.

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CERTIFICATE

This is to declare that this dissertation titled —“Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR)” is a bonafide work of Dr. Manisha Arthur towards the partial fulfilment of rules and regulations for the MD General Medicine examination of the Tamil Nadu Dr.M.G.R Medical University, Chennai to be held in May, 2018.

GUIDE

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ANTI- PLAGIARISM CERTIFICATE

Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR)

10,950 patients admitted in the general medical wards between 2016-2017 5,550 patients admitted in the

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GUIDE

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INTRODUCTION

Lung ultrasonography is an up and coming imaging modality which has been studied in the ICU and emergency department setting. It has been shown in multiple small studies that the sensitivity and specificity of the lung ultrasonogram is comparable to a CT scan of the chest.(1) It is cheaper, safer and also requires less expertise to operate.

This study was aimed at assessing the diagnostic utility of lung ultrasound in a general medical ward. We compared it prospectively to a composite standard which used clinical diagnosis, chest radiograph and relevant blood tests.

The setting was a medical college which caters to lower and middle income patients. The Principle investigator was given training in lung ultrasound and all scans done were checked by the lung ultrasound expert. All patients were those for whom the clinician ordered a chest radiograph for a clinical indication as an in-patient.

The findings of the ultrasound and the clinical composite outcomes were compared using sensitivity, specificity, predictive values and likelihood ratios.

As we did not exclude many patients we believe the results of our study could be generalised to any hospital in India with predominantly general medical patients.

AIM

To study the utility of bedside lung ultrasonography compared to a chest radiograph to diagnose common respiratory and cardiac conditions in a general medical ward.

OBJECTIVES

PRIMARY OBJECTIVE

To evaluate the sensitivity and specificity of bedside lung ultrasonography for diagnosis of different respiratory and cardiac conditions with a composite reference standard as the gold standard in a general medical ward.

SECONDARY OBJECTIVES

1. To assess the diagnostic accuracy of a post graduate resident in using lung ultrasonography to correctly diagnose various pathological conditions compared to a trained faculty.
2. To assess the diagnostic accuracy of a post graduate resident in using a chest radiograph to correctly diagnose various pathological conditions compared to a trained faculty.

LITERATURE REVIEW

HISTORY OF LUNG ULTRASOUND

Till very recently, the ultrasound was a tool only for radiologists. It was only cardiologists and obstetricians who used this modality for emergency purposes and it was not considered for use in the medical setting. Furthermore, the lung was not considered suitable for this imaging modality as air was considered an imperfect medium for sound waves to pass through.(2) Since 1989, François Jardin's ICU has studied the use of and made lung ultrasound an integral part of care in critically ill patients. It has only been after 25 years that the American College of Chest Physicians and La Société de Réanimation de Langue Française in France jointly proposed lung ultrasound as a standard of care.(3)

Since the early 90's, the use of ultrasound has exponentially increased from its use for ECHO's and vascular access to diagnose various lung pathologies.(4)

Till very recently, lung ultrasound has been undervalued because of the presence of ribs, sternum and aerated lungs which were not thought to be amenable to ultrasound. However, that perspective has changed with recent advances in the understanding of lung pathologies and the physics of ultrasound. For the basics and physics underlying the use of ultrasound in the human body, kindly refer Annexure 1.

INSTRUMENTATION

A number of new ultrasound machines are in the markets which boast of many cutting edge features. However, a simple machine is more than adequate to produce good quality images and come to an accurate medical diagnosis. The pre-requisites of a good machine are good resolution, ease of maintenance and low cost. (5) A probe with a frequency of 5 -7 Mhz with a small convex tip is ideal for a lung ultrasonogram.(6)

ULTRASOUND PROBES

The probes commonly used are linear, sector and curved probes. (7)

LINEAR ARRAY PROBES

They are high frequency probes (5-17 MHz) and hence, are used for imaging of superficial structures. They are used for vascular access, DVT screening and to diagnose superficial foreign bodies. It images very superficial structures and can image pleural thickening, sub-pleural consolidation and a small pneumothorax. This probe does not show anatomical relations and tends to obliterate artefacts.(8)



Figure 1 Linear array probe

CURVED ARRAY PROBES

They are low frequency probes which can penetrate deeper and is suited for abdominal work. The curvature of the probe brings out the B-lines and hence is useful in lung ultrasound.(9)



Figure 2 Curved array probe

SECTOR PROBE

It is a small probe with similar frequency to the curved array probe (1-5 MHz). It easily fits between the ribs and is preferred for cardiac screening. It has a poor spatial resolution and field detail and hence has a disadvantage in picking up superficial details such as pleural and sub-pleural pathologies.(10)



Figure 3 Sector probe

METHOD OF EXAMINATION

Patients can be examined in the supine, upright or lateral decubitus position depending on their clinical stability. The examination must be carried out in a systematic manner with all the lobes being subjected to a thorough examination. There are various protocols that define specific areas to be examined. (11) However, for an exhaustive

assessment, all areas similar to the auscultatory zones must be examined. That is the method we have employed in our study.(6)

NORMAL LUNG

Ultrasound of the pleura is very sensitive and specific. Normal pleura is seen as a smooth echogenic line with a hypo-echoic line below it. With recent high resolution imaging, the parietal and visceral pleura can be made out as two different lines. The phenomenon of lung sliding is the regular rhythmic movement between these layers which are separated by a thin layer of intra-pleural fluid.(12)

The parietal pleura is visualised as a fine echogenic line. Visceral pleura is more difficult to visualise. However, in the event of lung consolidation, the visceral pleura can appear as echogenic as the parietal pleura. There are certain characteristic findings present in a lung ultrasound which signifies a normal study. They are lung sliding, comet-tail artefacts and A lines. (13)

Comet-tail artefacts are formed by the reverberation echoes arising as a result of the irregularity of the lung surface which move with respiration.(14) They have a sensitivity of 100% and a specificity of 60% for normal lung. (12)

A-lines are also seen in normal lung as a result of reverberation artefacts which appear as bright white, hyper echoic, semi-circular repeating horizontal lines which are found deep to the pleural line. They do not move with respiration and are better viewed with a low frequency probe.(15)

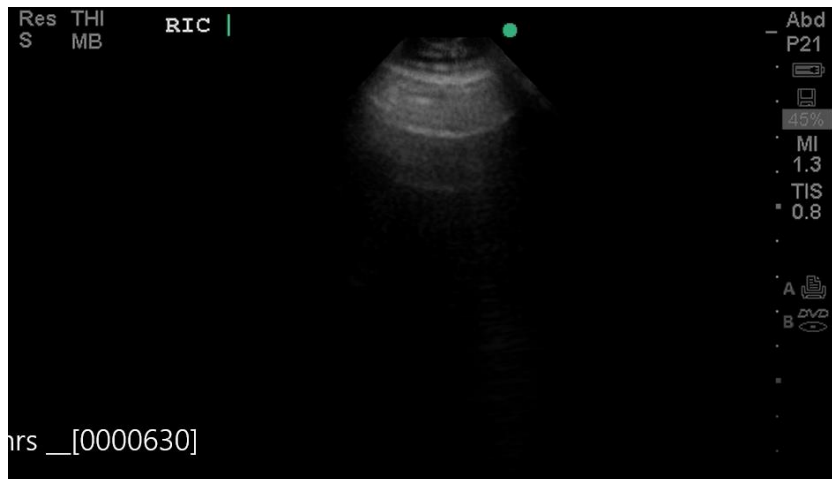


Figure 4. A- Lines

BLUE PROTOCOL

In most studies, it is the BLUE protocol that was used to study the lung systematically and arrive at a reasonable respiratory diagnosis. In the BLUE protocol there are 3 points on each hemi-thorax that cover the majority of the lung and avoid the heart as much as possible. There were a total of 9 profiles that were described by Lichtenstein et al. and it was with these profiles, that a final respiratory diagnosis was made.(16) More details on this protocol is found in Annexure 2. However, we thought that the use of the BLUE protocol would show a poor representation of the lower lobes of both lungs. In our study, seven points on each hemi- thorax were studied just as in auscultation.

PLEURAL EFFUSION

Chest radiograph has always been the standard for detecting a pleural effusion. However, a portable film and supine films can easily miss small effusions. Blunting of the costo-phrenic angle takes place when there is a minimum of 150-200 ml of fluid.(17) In a lateral chest radiograph, as little of 50 ml can be picked up. However, in a lung ultrasound, as little as 20 ml can be detected.(18) Ultrasound for detection of an effusion is also helpful in the case of an opaque hemi-thorax where the cause of opacity cannot be made out on radiograph. (19) The use of ultrasound in detecting effusions is particularly important for USG guided thoracocentesis. In order to carry out a thoracocentesis, the depth of the effusion must be at least 1 cm and should be free of loculations. (19)

METHOD

A low frequency probe is used with the patient in the upright position or with head elevated. The best location to look for an effusion is in the mid-axillary line in a sub-diaphragmatic location with the probe angled upwards to look above the solid organs.

In an effusion, there is a dark anechoic space above the diaphragm with absence of the mirror artefact.

SONOGRAPHIC SIGNS

The parietal pleural line is fixed whereas the visceral pleural line moves with each respiratory cycle. This inter-pleural distance decreases with each inspiration which is seen as sinusoidal waveform on M mode. This inspiratory shifting of the pleura with apparent decrease in the size of the effusion is known as the sinusoid sign and is specific for pleural effusion.(16)



Figure 5 Pleural Effusion

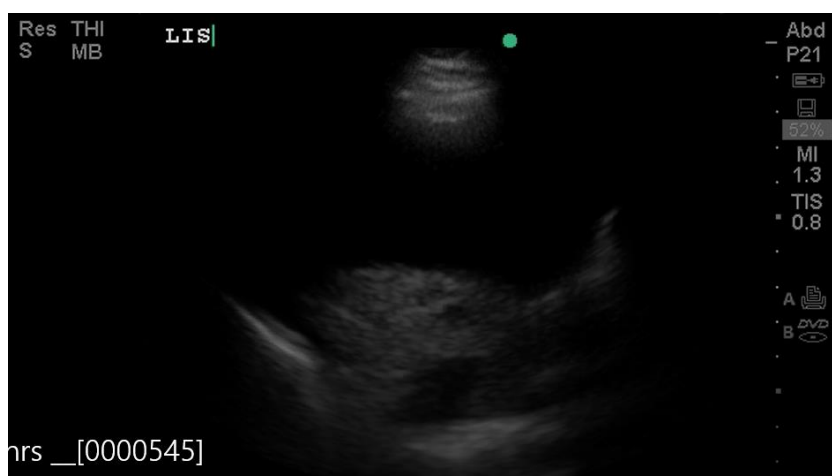


Figure 6 Pleural Effusion

The various aetiologies can be delineated to a certain extent. In case of a transudative effusion, it is usually anechoic and homogenous because the fluid contains no ultrasound reflectors. According to the type of the pleural effusion, it can appear as anechoic (black), complex non-septated (black with white strands), complex septated (black with white septa), or homogeneously echogenic (white).(19) An exudative process is characterised by complex, echogenic, septate effusions with particles within the fluid.(20) Homogeneous echogenic effusions are usually hemorrhagic effusions or empyema.

The lung pulse or the fluid colour sign is useful in differentiating between effusions and pleural thickening. There is movement of the effusion echoes with the respiratory or cardiac cycles in the case of an effusion and this has a sensitivity of 89% and a specificity of 100%.(12)

Empyema will show densified echoes with irregular signals at various positions. Malignant pleural effusions are often more echogenic than echo free and are often accompanied by pleural thickening and nodules.(21)

The use of ultrasound for pleural taps decreased the rate of complications like pneumothorax and also increases the success of fluid removal when compared with a blind method. (22)

OTHER STUDIES

Lung ultrasound has a higher accuracy in detecting pleural effusion in comparison with bedside chest X-rays (93% vs. 47%). (23) This study compared these imaging modalities with clinical findings by experienced physicians. A study done with a computed tomography of the thorax as a gold standard, showed that the CXR had a sensitivity of 65%, a specificity of 81% and a diagnostic accuracy of 69%. Ultrasound, on the other hand had a sensitivity of 100%, specificity of 100% and a diagnostic accuracy of 100%.(24) However, this study included both symptomatic and asymptomatic patients. In another study which included symptomatic patients with CT as a gold standard, there was a high concordance between USG and CXR (K=95%). It was also found that USG showed greater sensitivity than a CXR in patients with a non-loculated effusion. It was also much faster to obtain a diagnosis than to wait for a conventional chest radiograph.(25)

A meta- analysis was done in 2010 on four studies and it was found that the mean sensitivity and specificity in detecting an effusion was 93% (95% confidence interval, CI: 89% to 96%) and 96% (95% CI: 95% to 98%) respectively. However, there was an absence of a sensitivity analysis, very few surveys were included and there was significant publication bias. (26)

A more extensive meta- analysis was done in 2016 which included 12 studies and 1554 subjects. Only studies that used a gold standard of computed tomography or surgery to confirm the presence of pleural effusion were included in the meta-analysis. Pooled sensitivity and specificity of lung ultrasonography was 0.94 (95% CI: 0.88-0.97; I²= 84.23, p<0.001) and 0.98 (95% CI: 0.92-1.0; I²= 88.65, p<0.001), respectively compared to 0.51 (95% CI: 0.33-0.68; I²= 91.76, p<0.001) and 0.91 (95% CI: 0.68-0.98; I²= 92.86, p<0.001), respectively for chest radiograph. It was also found that an effusion was more likely to be detected if the ultrasonogram was carried out by an intensivist or a radiologist.(27)

PNEUMOTHORAX

Pneumothorax is a common finding in the emergency department and the ICU. It is also a common complication with relation to central venous access. The diagnosis of a pneumothorax is usually by a chest radiograph. In most cases, however, the patient is too sick and to obtain a chest radiograph is time consuming. Ultrasound was used as an imaging modality for pneumothorax since 1987. (28) Small or medium size pneumothoraxes are usually not life threatening and no emergency intervention is required. However, a delay in diagnosis of these small pneumothoraxes can lead to it's progression and hemodynamic instability.(29)

METHOD

A higher frequency probe (5-13 MHz) is preferred with the patient in an upright position. (30) The probe is placed in the second or third intercostal space in the mid-clavicular line as air rises to the least dependent part of the chest. In a supine position, this is the anterior part of the chest in the second and third intercostal space. (30)

SONOGRAPHIC SIGNS

In normal aerated lung, the most cardinal feature is the presence of lung sliding. B-lines are discrete, laser like reverberation artefacts that arise from the parietal pleura and are seen in normal lung. They extend to the bottom of the screen and move with lung sliding.(31)

In M-Mode, a normal lung will show two different appearances – stationary and linear repeating lines closer to the pleural line with an irregular choppy appearance deeper to the pleural line signifying lung. This is known as the seashore sign.(32)

The hallmark signs of a pneumothorax are absence of lung sliding, absence of B-lines and presence of the lung point. (33)

In a patient with pneumothorax, there is absence of lung sliding because of accumulation of air between the two layers of pleura and this collection of air prevents

the detection of normal lung sliding. (34) Absence or decrease in lung sliding is seen in other conditions like acute respiratory distress syndrome (ARDS), pulmonary fibrosis, large consolidations, pleural adhesions, atelectasis, right main stem intubations and phrenic nerve paralysis. (35)

The lung point sign is specific for detection of a pneumothorax. It is seen in an incomplete pneumothorax when the air between the layers of pleura abuts the normal pleura at a point called the lead point. Therefore, in the same field, there will be absence of lung sliding in one area with normal lung sliding and comet tail artefacts in the other. The presence of lead point has a specificity of 100% to detect a pneumothorax.(36) However, the sensitivity is relatively low (66%).(36)

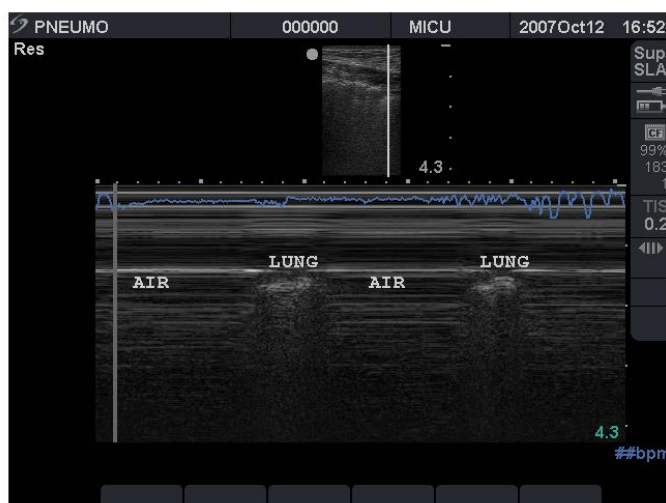


Figure 7 Pneumothorax (Used with permission from Pitchamuthu K. – criticlecho.com)

The M- Mode can also be used to confirm the presence of a pneumothorax. In a pneumothorax, as there is no lung sliding, there is only linear repeating lines seen with

the absence of the irregular appearance of the lung. This is known as the stratosphere or barcode sign.(37)

Pneumothorax cannot be picked up in the case of extensive subcutaneous emphysema or a large pleural effusion.(38) Figure 7 shows how horizontal lines have replaced the granular appearance of normal lung suggesting a pneumothorax.

OTHER STUDIES

In the setting of trauma, the use of lung ultrasonography was studied to a chest radiograph alone, a composite standard (CXR, CT, clinical course and invasive interventions) and CT alone. Lung ultrasonography was found to have a sensitivity of 58.9% with a positive likelihood ratio of 69.7 and a specificity of 99.1% in comparison to the composite standard. It was also compared to CXR with CT as the gold standard and was found to have higher sensitivity (48.8 % vs. 20.9%) and a similar specificity (99.6% vs. 98.7%).(39) Another study also noted that up to 76% of occult pneumothoraxes were missed by the initial AP chest radiograph in a study of trauma patients.(40)

In the ICU setting, it has been shown that the ultrasound has a sensitivity of 95.3% and specificity of 91.1% in picking up a pneumothorax with CT as the gold standard.(41)

In an Indian study, the sensitivity and specificity were slightly lower (89% and 88.5%) when CT was taken as the gold standard. They also found that the average time taken to do the ultrasonogram was less than 2 minutes.(42)

A meta – analysis carried out in 2011 which included 20 articles, showed that the pooled sensitivity and specificity were 0.88 and 0.99 for lung ultrasonography and 0.52 and 1.00 for the chest radiograph. There was no significant difference in the sensitivity and specificity when the ultrasonogram was carried out by a clinician other than a radiologist.(43) A meta- analysis carried out 1 year later showed similar results. (44) The most recent systematic review by Azad et al. echoed these results and suggested the addition of lung ultrasonography in the guidelines used to diagnose a pneumothorax.(45)

CONSOLIDATION

Pathological processes can be detected by ultrasonography when aerated lung is replaced by consolidated lung.(7) Consolidation is a umbrella term which includes any pulmonary pathology which converts aerated lung to have a tissue like echo texture.(46) Additional signs help in differentiating between the various pathologies.

METHOD

The probe used is usually a low frequency probe. If a sub-pleural consolidation is suspected, a higher frequency probe is used. Most pulmonary pathology extends into the pleura and hence, a pneumonic consolidation can usually be picked up on ultrasound examination of the relevant lung areas. (47)

SONOGRAPHIC SIGNS

A pneumonic lung exhibits a liver like echo texture. Air and fluid bronchograms can be seen within consolidated lung. Air bronchograms are dynamic and echogenic foci that fluctuate with the respiratory cycle.(48) Fluid bronchograms on the other hand are seen as anechoic tubular structures which represent fluid filled airways.(49) Alveolar consolidations have dynamic bronchograms in contrast to atelectasis which had static bronchograms. This finding was found to have a specificity of 94% and a positive predictive value of 97%. (50) Ultrasonogram is ideal to differentiate between dense consolidations and pleural effusions.(51)The presence of multiple B-lines signify the presence of an interstitial syndrome rather than a pneumonic consolidation.(52)

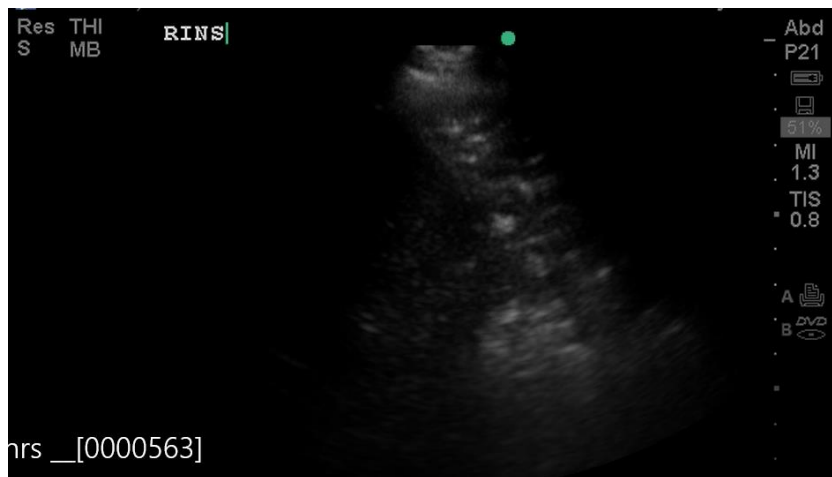


Figure 8 Consolidation

OTHER STUDIES

In the emergency department setting, patients who presented with a clinical diagnosis of pneumonia underwent a CXR and a ultrasonogram and this was compared with a final clinical diagnosis of pneumonia. It was found that the sensitivity and specificity of ultrasonogram was much higher than CXR (98.5% vs. 73.5%) and (64.9% vs. 59.5%).(53) Another study including close to 200 patients, used CT as a gold standard. They found that the sensitivity, specificity, and accuracy for ultrasonography and CXR were 94.6% versus 77.7% ($p<0.001$), 98.5% versus 94.0% ($p=0.940$) and 96.1% versus 83.8% ($p<0.001$), respectively.(54) A larger study with CT as gold standard, showed that when a sub- group analysis including patients with pleuritic chest pain was done, both sensitivity and specificity improved. (55) A large European study which used CT as the gold standard, showed a positive likelihood ratio of 40.5 and a negative likelihood ratio of 0.07. On combining ultrasonogram with auscultation, the positive LR increased to 42.9 and the negative LR decreased to

0.04.97.6% of patients had breath-dependent motion of infiltrates, 86.7% an air bronchogram and 54.4% a basal pleural effusion.(56) Most of these studies have been carried out in the emergency department or ICU setting. A small study done looking at the ability to rule in or rule out pneumonia in a stroke, showed a concordance between ultrasonogram and CT of 66.7%.(57)

A meta- analysis done in 2014, included 10 articles with 1172 patients. The gold standard varied from a CT to a composite reference standard. The pooled sensitivity and specificity were 94% (95% CI, 92%-96%) and 96% (94%-97%), respectively. The area under the ROC curve was 0.99 (0.98 – 0.99).(58) Multiple other meta- analyses have shown similar results. (59)(60)(61) When the hospital diagnosis was used as the standard, a pooled sensitivity of 95% for LUS compared with 77% for CXR was obtained. (60) The most recent of them showed a pooled sensitivity and specificity of 0.85 (0.84–0.87) and 0.93 (0.92–0.95), respectively. The area under the pooled ROC (AUC for SROC) was 0.978.(62)

A particular area of interest is the ability of the ultrasonogram to pick up a consolidation before it can be picked up on a chest radiograph. A study done by Bourcier et al. studied the ability of the ultrasonogram to detect pneumonia from the time of onset of symptoms. This study compared patients with signs and symptoms for less than 24 hours to those with symptoms for more than 24 hours. It was found that the sensitivity of the ultrasonogram was much higher than the radiograph in the group of patients with symptoms less than 24 hours (76% vs. 23%).(63) This imaging modality has also been found to be cost effective for the diagnosis of pneumonia. (64)

A concern on the use of lung ultrasonography was whether this modality would change the course of management. A study on ICU patients with new suspected respiratory disease or a deterioration the ABG, showed that the ultrasonogram findings resulted in a change in management in almost half of the patients. In 21% of the patients, there was no clinical suspicion of a respiratory disease.(65)

ACUTE ALVEOLAR INTERSTITIAL SYNDROME

It is a group of conditions which refer to involvement of the interstitium resulting in impaired gas exchange. The underlying pathophysiology is leakage of fluid into the pulmonary interstitium and alveolar spaces. (66)

METHOD

A low frequency probe is used and every area of the chest is examined, ideally in the sitting position.

SONOGRAPHIC SIGNS

Interstitial fluid and alveolar fluid is seen as B-lines on lung ultrasound. These are vertical hyper echoic artefacts formed secondary to reflection of the waves at the interlobular septa.(67) They can be described by seven criteria.

1. It always arises from the pleural line

2. It always moves with lung sliding
3. It is long and reaches the edge of the screen
4. It is always a comet tail artefact
5. It is well defined and laser like
6. It obliterates A-lines
7. It is hyper echoic like the pleural line. (11)

The importance of these criteria is to distinguish B-lines from other artefacts such as Z-lines and E-lines. Z-lines are shorter artefacts that are seen at the pleural interface and do not reach the edge of the screen. E-lines are very similar to B-lines but arise above the pleural line indicating subcutaneous emphysema.(15) Lung rocket is used to describe three or more B-lines between two ribs and is called so because it mimics the exhaust gas after a rocket launch. (68) They correlate with interstitial syndrome with 100% accuracy when compared to CT.(68)

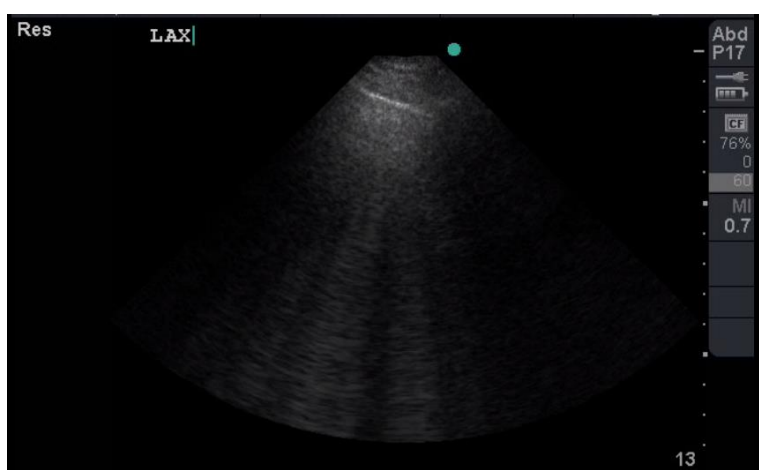


Figure 9 Blines>3

PULMONARY EDEMA

Ultrasound findings precede those of radiography and are very useful for the diagnosis of pulmonary edema with a sensitivity and specificity of 97% and 95%, respectively.(69), (68) At least 3 B-lines must be seen in each zone of the lung for it to be called pathological B-lines.(70) Other findings that contribute to a diagnosis of cardiogenic pulmonary edema is the presence of pleural effusion, distension of inferior vena cava and poor cardiac contractility.(71)

ACUTE RESPIRATORY DISTRESS SYNDROME

ARDS is also characterised by diffuse alveolar damage with fluid in the interstitium and alveolar spaces. In ARDS, B-lines are multiple and are inhomogeneous with small sub-pleural consolidations in the basal part of the lung. There can also be air bronchograms within these consolidations which help distinguish ARDS from cardiogenic pulmonary edema.(72)

The sonological differences between pulmonary edema and ARDS are given in Table 1.(73),(74)

Table 1 Sonological differences between pulmonary edema and ARDS

	Pulmonary Edema	ARDS
Clinical setting	Acute	Acute
Distribution of B lines	Bilateral and symmetric	Non -homogenous with spared areas
Effect of diuresis on B lines	Reduction	No effect
Pleural line abnormalities	Absent	Present, typical
Lung sliding	Normal	Reduced or absent
Consolidation	Absent	Frequent in the posterior areas
Pleural effusion	Very frequent and large	Common but small

OTHER STUDIES

A study done on the accuracy of ultrasonogram to diagnose pulmonary edema, used CXR, wedge pressure and extravascular lung water as the gold standard. Significant positive linear correlations were found between ultrasonogram and wedge pressure.(75) The B-lines on ultrasonogram showed a sensitivity of 80.60% and a specificity of 77.60% with a PPV of 65.80% and a NPV of 88.20% in the diagnosis of cardiac pulmonary edema compared to CXR which showed a sensitivity of 74.20%, a specificity of 69.00%, a PPV of 56.10% and a NPV of 83.30% in the diagnosis of

cardiac pulmonary edema.(76) A meta- analysis which included 7 articles with a total of 1,075 patients showed a sensitivity of using B-lines for detection of pulmonary edema of 94.1% (95% confidence interval [CI] = 81.3% to 98.3%) and a specificity of 92.4% (95% CI = 84.2% to 96.4%). (77)

INTERSTITIAL PNEUMONIA

During the course of the study, we encountered a large number of patients suffering from interstitial pneumonia secondary to H1N1 influenza. A chest radiograph fails to pick up early stages of the disease. One study carried out in 2009, showed that lung ultrasonogram had a sensitivity of 94.1% and specificity of 84.8% in picking up an interstitial pneumonia when a composite standard was used as reference.(78)

COMPOSITE REFERENCE STANDARD

An ideal gold standard for a lung pathology would be a lung computed tomography. However, this was not feasible keeping in mind both financial and ethical reasons. On an extensive literature review, it was found that a number of similar studies have been carried out with the reference standard as a composite reference standard which included clinical details, lab parameters, limited radiology and the final diagnosis at discharge. (57,79), (80), (81), (82), (83). The largest of these is the study carried out by Lichtenstein et al, which included a total of 260 patients. The sensitivity and specificity were studied separately for different pathologies. It was found to be 97%

sensitive and 95% specific for pulmonary edema, 89% sensitive and 94% specific for pneumonia and showed 81% sensitivity and 100% specificity for pneumothorax. (5)

LEVEL OF TRAINING

In most of the earlier studies, the ultrasonogram was performed by a radiologist. However, there have been recent studies to evaluate the level of training required to carry out a lung ultrasonogram. In one study, the inter-observer agreement between a LUS expert with 5 years of experience and a resident with 1 year experience was found to be high ($k = 0.83$). (55) In a larger study, the performance of non- experts to identify a lung pathology was studied. 5 hours of training was given followed by 10 supervised ultrasound studies. With the final diagnosis used as the gold standard, the sensitivity and specificity for the diagnosis of pneumonia was found to be 88% and 90%, which was comparable to other studies.(5) A study by See et al. showed that a respiratory technician was able to acquire acceptable images in 98% of cases and interpret them 95% of the time, with only brief training and 10 supervised studies.(84) A small study was done which studied the ability of residents to recognise pulmonary edema on ultrasonogram and CXR. The overall interpretation of pulmonary edema was better with ultrasonogram than chest radiograph. It was also found that the emergency medicine residents interpreted the ultrasonogram more accurately than the internal medicine residents and also that the radiology residents were better than both the internal medicine and emergency medicine residents. (85) This shows that basic training is sufficient to make a reasonable pulmonary diagnosis using an

ultrasonogram. The United States has already made basic ultrasonogram training part of the residency program. Two studies done showed that it was well accepted and used and is crucial for resuscitation and diagnosis. (86)(87)

GLOBAL DATA ON LUNG SONOLOGY IN GENERAL MEDICINE

Most studies that have been done have been carried out in the ICU setting or in the emergency department setting. One study by Reissig et al (56) clearly mentions the setting of the ward as a medical ward. The reference test was a chest radiograph or a CT scan in case of inconclusive findings. Lung ultrasonogram showed a sensitivity of 93.4% (95% CI, 89.2%-96.3%) and a specificity of 97.7% (95% CI, 93.4%-99.6%), Likelihood ratios were also calculated and were found to be 40.5 (95% CI, 13.2-123.9) for positive and 0.07 (95% CI, 0.04-0.11) for negative results. There was another smaller study that was carried out in a stroke unit which showed a reasonable sensitivity and specificity. (88) An extensive search did not find any more studies that were carried out exclusively in a medical ward. This was important, to see if there was a difference in the sensitivity and specificity in case of more stable patients and if lung ultrasonogram was useful only in a sicker subset of patients.

INDIAN DATA

On an extensive search of Indian literature, which included published papers and trials in progress, only two review articles and one published study was found. A review article by Saraogi et al. reviewed the basics of ultrasonogram and lung ultrasonogram and the various findings in different conditions. The specificity and sensitivity of this imaging modality was not studied. (89) A similar Indian review article described the BLUE and FALLS protocol and its use in the ICU setting. This article expressed the need for comparative studies in an OPD/ general ward setting.(90) There was one published study which studied the sensitivity, specificity, positive and negative predictive value of LUS in diagnosis of pneumothorax in hemodynamically stable patients. (91)

DIAGNOSTIC DILEMMA

All the studies that have been quoted above have been carried out in either an ICU or emergency department setup. There have been very few studies to show the utility of bedside lung ultrasonogram in a general medical ward or in an Indian setting. The utility in a general medical ward which has numerous patients with varied chest diseases is uncertain.

LACUNAE IN CURRENT KNOWLEDGE AND JUSTIFICATION

There have been no studies to our knowledge from India, which assess the use of lung ultrasound in the general ward setting. Furthermore, it would be useful to study the expertise required to carry out a lung ultrasonogram and the ability of a resident to interpret the same. Although theoretically the patient population is the same, will there be differences in the sensitivity and specificity when carried out in patients who are not acutely ill and how will this change management? If there is significant difference in sensitivity and specificity between the ultrasonogram and chest radiograph, would it be useful to make it part of standard of care? And can we do away with the chest radiograph? If this study showed significant results, it would also be useful to include lung ultrasonogram training as a part of the resident training process.

STUDY HYPOTHESIS

The study hypothesis is that bedside lung ultrasonography can be used as a simple bedside test to diagnose common respiratory and cardiac conditions in the ward and that its sensitivity and specificity is better when compared to a chest radiograph.

MATERIALS AND METHODS

This was a prospective diagnostic test study conducted at the Christian Medical College, Vellore over the years 2016-2017. The study protocol was approved by the Institutional Review Board, with IRB Min. No. 9820 dated 07.01.2016. (Annexure7)

This aim was to evaluate the diagnostic utility of chest ultrasound in a general medical ward.

Informed consent was taken from the patient/ patient's relatives prior to inclusion in the study. (Annexure 3).

PATIENT POPULATION

We included all adult patients admitted in the general medicine ward of Christian Medical College, Vellore between June 2016 and August 2017. All patients had either new onset cardiac or respiratory symptoms or signs for which a chest radiograph was done. All eligible patients were consecutively recruited

Selection was independent of results of the index test. The whole sample received administration of both tests in a blind manner.

INCLUSION CRITERIA

1. Age 18 years or older
2. Patients presenting with respiratory or cardiac complaints or signs for whom a CXR was done
3. In-patients with new onset respiratory or cardiac complaints or signs for whom a CXR was done

EXCLUSION CRITERIA

1. Age less than 18 years
2. Woman who are pregnant
3. Subcutaneous emphysema over the chest

SETTING

This study was carried out in the general medical wards C, E, I and MTS - 4 of Christian Medical College and Hospital, Vellore.

DEFINITION OF A CASE

The patients were consecutively included in the study if they had the following symptoms or signs following which a CXR was done –

1. Cough
2. Breathlessness
3. Chest pain
4. Haemoptysis
5. Decreased breath sounds
6. Crepitation (Coarse or fine) or wheeze
7. Bronchial breath sounds
8. Pleural rub
9. Fever spike
10. Desaturation
11. Tachypnoea

Patients with any of the above symptoms, who fulfilled the inclusion and exclusion criteria underwent both CXR and Chest Ultrasound within 24 hours of each other.

VALIDATION OF ULTRASOUND TECHNIQUE

The primary investigator underwent a brief training session with the expert in chest ultra-sonogram. She evaluated 20 chest ultrasonograms which were then verified by a trained chest –sonogram specialist (Dr K. Pitchamuthu). The correlation - kappa co-relation, to determine the level of agreement between the principal investigator and the expert in lung ultrasonogram was found to be 0.77 [95% CI, 0.34-1] which indicated substantial correlation and then the study began.

CHEST X-RAY

Chest X-ray (Posterior-anterior view) was carried out using standard procedures in the radiology department (Annexure 4). For patients who were too sick to be moved to radiology, a portable chest radiograph (Antero-posterior view) was done (Annexure 5). The CXR was reported by the primary treating physician who was an internal medicine faculty (who was also aware of clinical details and other investigations) initially and then by a trained radiologist (who was aware of the clinical details only).

EXPERIMENTAL TEST

The chest ultra-sonogram was carried out by the principal investigator with only knowledge of the clinical information. The USG machine used was the Sonosite Micromaxx and the probe used was the P17 probe (1-5MHz). However, in view of technical problems, the machine had to be changed midway through the study. The new machine used was Sonosite M-Turbo and the probe used was the P17 probe (1-5MHz).



Figure 10 Sonosite Micromaxx



Figure 11 Sonosite M- Turbo



Figure 12 P17 probe

All patients were placed in a semi-recumbent form during the examination. The ultrasound was carried out within 24 hours of the CXR being taken to ensure no change in the clinical condition of the patient during this time period. However, in cases of acute pulmonary edema, there was a chance of worsening or improvement of signs as time progressed. Hence, they were excluded from the study if there was a drastic change in symptoms as opined by the primary treating physician.

The lung ultrasound was carried out on 7 points on each hemi-thorax – each point roughly co-relating with the points of auscultation. The points on each hemi-thorax were –

1. Infra- clavicular
2. Mammary
3. Axillary
4. PLAP's point
5. Supra-scapular
6. Inter-scapular
7. Infra-scapular

However, in sicker patients who could not be easily turned in bed, a 4 point test was done which included the infra-clavicular, mammary, axillary and PLAP's point on each side. The same patient could enter the study multiple times if the duration

between recruitment times at both instances was at least 1 week. All ultrasound images and videos were saved, verified and stored. All scans images were reviewed by the chest sonologist.

The Clinical Research form (CRF) was filled by the primary treating physician who interpreted the CXR and the principal investigator who did the lung ultrasonogram. (Annexure6)

REFERENCE STANDARD

An ideal gold standard for a lung pathology would be a lung computed tomography. However, this was not feasible keeping in mind both financial and ethical reasons. On an extensive literature review, it was found that a number of similar studies have been carried out with the reference standard as a composite reference standard which included clinical details, lab parameters, limited radiology and the final diagnosis at discharge. (57,79), (80), (81), (82), (83). The largest of these was a study carried out by Lichtenstein et al, which included a total of 260 patients. The sensitivity and specificity were studied separately for different pathologies. It was found to be 97% sensitive and 95% specific for pulmonary edema, 89% sensitive and 94% specific for pneumonia and showed 81% sensitivity and 100% specificity for pneumothorax. (5)

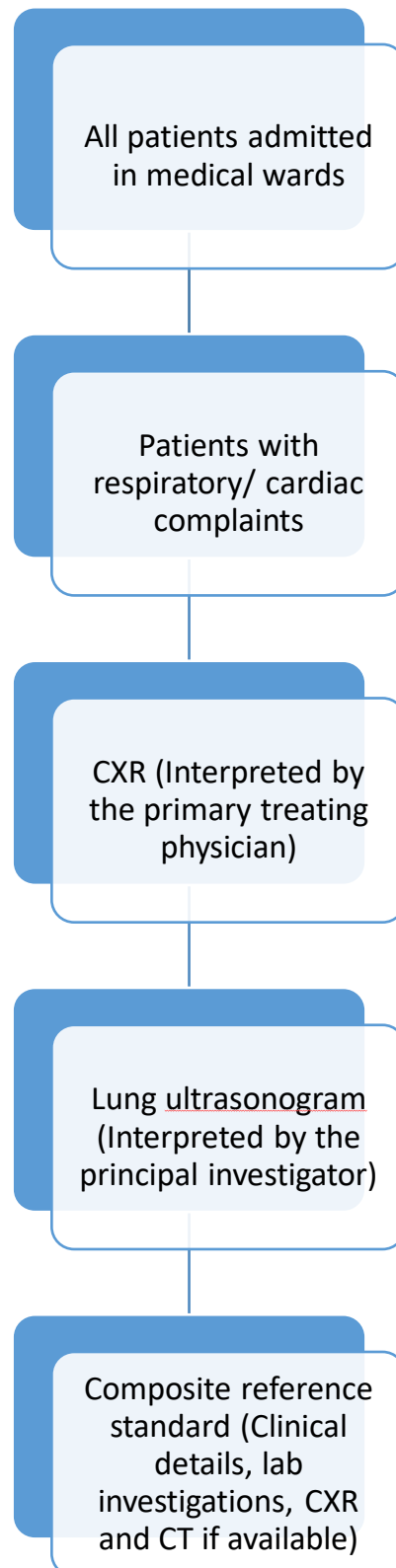
The consultant physician who was treating the patient made the final diagnosis (composite reference standard) of the chest condition. This was based on clinical presentation, blood investigations and radiological features (CXR and CT if it was done).

For the first 54 patients, the treating physician was also informed of the chest sonology report. This has a known bias of the new diagnostic test being part of the reference standard. We analysed the data in which the chest sonology was part of the reference standard and when it was not to study this effect. The results are reported together and separately.

We use the reference standard mentioned above to study the diagnostic test characteristics of the chest sonogram. We calculated the sensitivity, specificity, predictive values as well as the likelihood ratios. We also analyzed the ability to correctly diagnose individual pathological conditions.

Un-interpretable or intermediate test results were treated as negative and all missing data was treated as missing.

FLOW CHART





STATISTICS

SAMPLE SIZE CALCULATION

According to a very similar study which employed a similar strategy,(92) the sensitivity and specificity of the lung ultrasound was 88% and 90% respectively (taken for identification of pneumonia, assuming that would be the most common pathology observed). There were no studies which used a composite reference standard. For a power of 80% and an alpha error of 5% our calculated sample size was 435 patients. To account for missing and unclear data, a total of 450 participants were included in the study. N-master 2.0 software (Department of biostatistics, CMC Vellore) was used for sample size calculation. The sensitivity analysis for the sample size calculation is shown below

Diagnostic Test - Comparing the sensitivity of the new test with reference test		
Sensitivity/Specificity of the new test (%)	88	90
Sensitivity/Specificity of the reference test (%)	95	95
Difference	7	5
Power (1- beta) %	80	80
Alpha error (%)	5	5
1 or 2 sided	2	2
No. of diseased subjects needed	248	435

Figure 13 Calculation of sample size

TYPE OF DATA AND METHOD OF ANALYSIS

Data from the CRF were entered into the Epidata v 3.1 data entry software and then exported to SPSS version 17, IBM Corporation for analysis. All analysis was performed by trained biostatisticians (Mrs. Reka K. and Mr.Bijesh Yadav).

For continuous data such as age, the descriptive statistics Mean, SD, Median, Minimum and Maximum are presented. For categorical data, the number of patients and percentage are presented. Based on the normality of data, the parametric t test or nonparametric Mann -Whitney test were applied to the data. The Chi-square or Fisher exact test was applied to the data when required.

The level of agreement among observers for the ultrasound and chest radiograph and the interpretation by the experts was evaluated with the kappa reliability test: kappa values < 0 indicated less than chance agreement; kappa values of 0.01-0.20 indicated slight agreement; kappa values of 0.21-0.40 indicated fair agreement; kappa values of

0.41-0.60 indicated moderate agreement; kappa values of 0.61-0.80 indicated substantial agreement; and kappa values of 0.81-0.99 indicated almost perfect agreement. Sensitivity and specificity of the techniques will be calculated. All tests will be two-sided at $\alpha=0.05$ level of significance.

Sensitivity, specificity and kappa co-efficient was calculated using the diagnostic test calculator by Alan Shwartz and the VassarStats online calculator. (93), (94)

FUNDING AND APPROVAL

The protocol was approved by the institutional review board and the funding was provided by the FLUID grant of the IRB and the Medicine 2 Special fund. (Annexure 8).

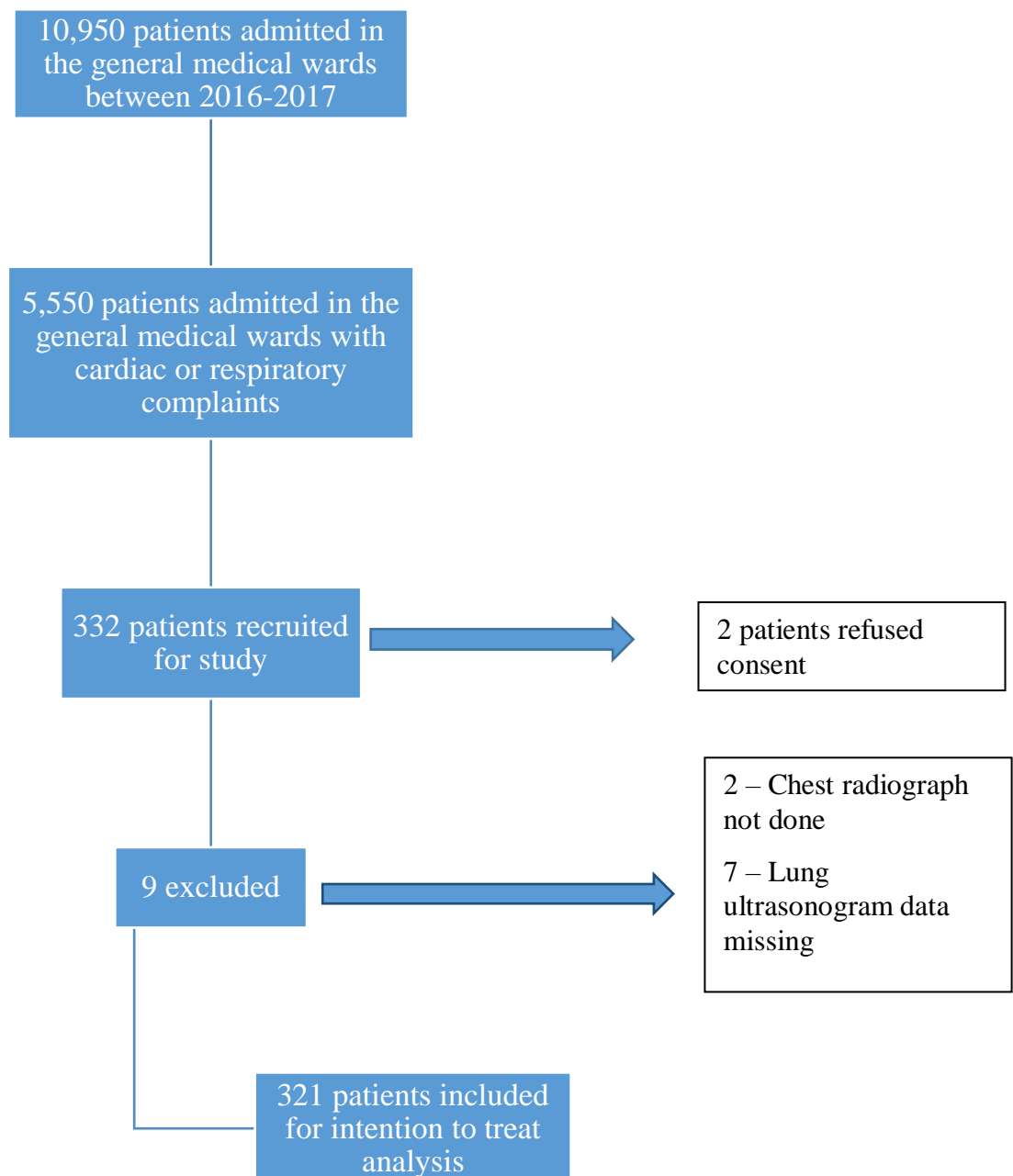
STARD CHECKLIST

The planning and reporting of our study was done following the STARD guidelines (Standards for Reporting Diagnostic accuracy studies) (95)(Annexure 9).

RESULTS

The clinical assessment and documentation was carried out for a period of 2 years from June 2016 and August 2017. 321 patients fulfilled the inclusion criteria and were enrolled for the study after obtaining informed consent. This study included 331 patients of which 9 were excluded because of various reasons.

STROBE FIGURE



DEMOGRAPHIC OF PATIENTS

The median age of the patients included in the study was 49.30 with the majority of patients being in the age group between 41 – 75 years of age. 177 (55.14%) included were males.

Figure 14 Sex distribution

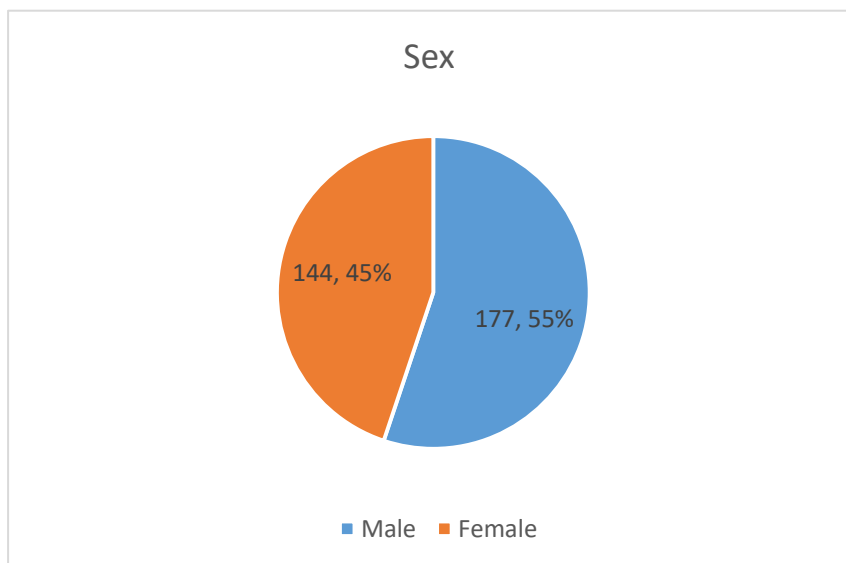
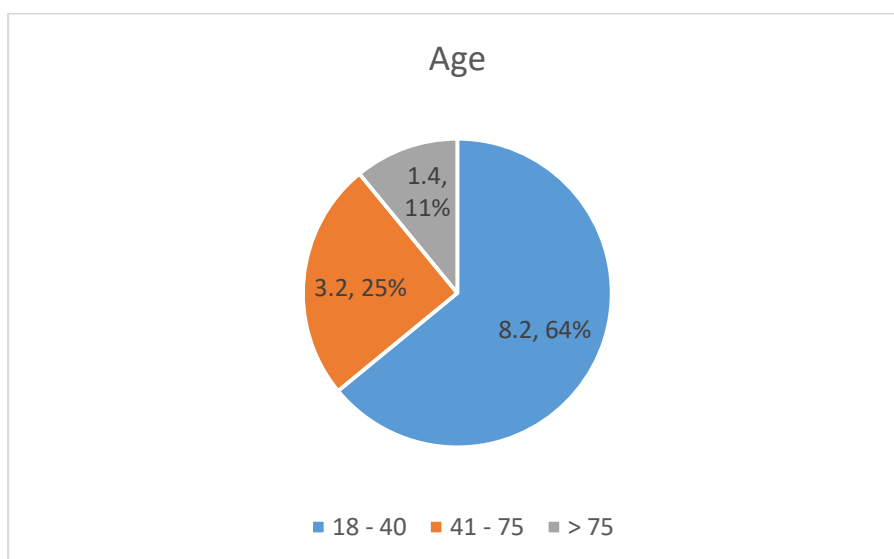


Figure 15 Age distribution



Co-morbidities

A large proportion of the patients included in the study had other underlying co-morbidities which could have influenced the findings and outcomes. 110 (34.2%) of the patients had diabetes and 93 (28.9%) had hypertension. Other important risk factors were the presence of an obstructive airway disease (20, 6.23%) and history of tuberculosis in the past (14, 4.36%).

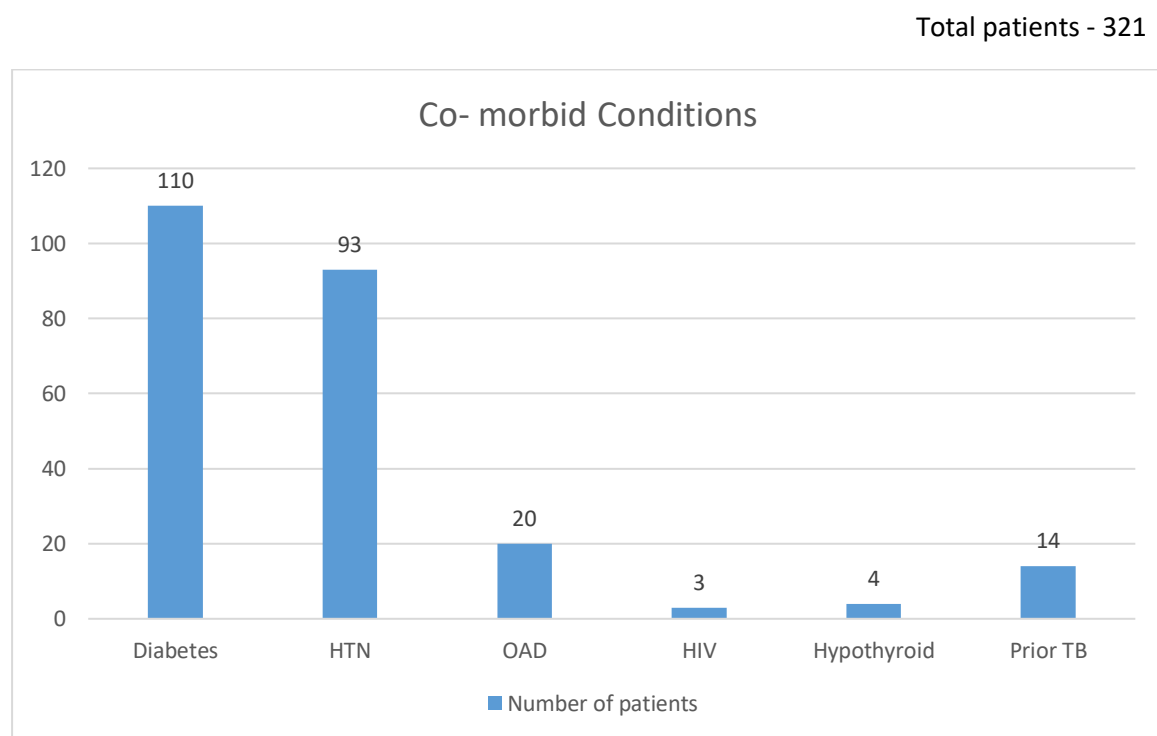


Figure 16 Co-morbidities

Clinical Condition

Out of the 321 patients that were included in the study, all of them had either signs or symptoms of respiratory or cardiac disease. The time period between the onset of illness and the ultrasound was also documented. Majority of the patients (153, 47.66%) had a history which lasted for more than 7 days.

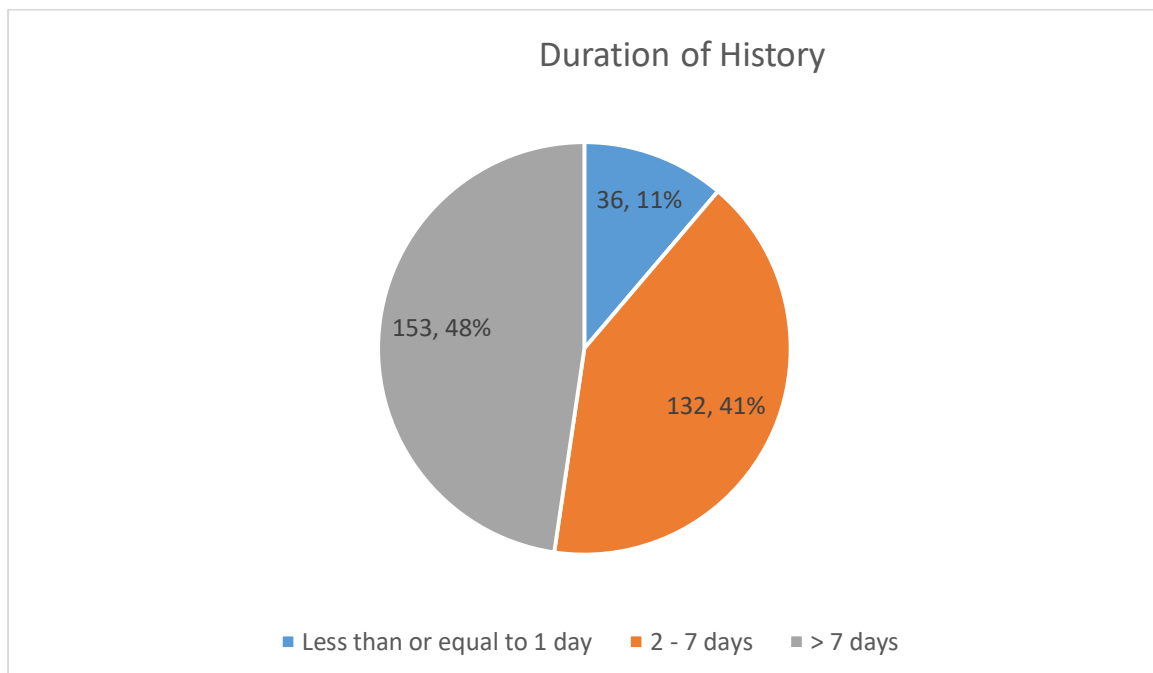


Figure 17 Duration of history

The most common symptom encountered was breathlessness (250, 77.88%). Other symptoms are as shown in Table 2. Out of the 321 patients, 94 (29.28%) had a normal clinical examination.

Table 2 Symptoms

Symptom	Number of patients	Percentage (n=321)
Cough	106	34.19%
Breathlessness	250	77.88%
Chest pain	18	5.61%
Haemoptysis	2	0.6%
Fever	183	57.01%

Severity of disease

4 (1.25%) of the patients were ventilated which included intubated and patients on non-invasive ventilation. Patients who were receiving oxygen support were considered to be not ventilated.

In 25 (7.79%) of the patients, the lung ultrasound was done in the supine position which could have affected the quality of the study. In 71 (22.12%) of the patients, only a portable radiograph was done for which interpretation would have been difficult.

Table 3 Severity of disease

	Number of patients	Percentage (n=321)
Ventilated	4	1.25%
Supine	25	7.79%
Portable radiograph	71	22.12%

These variables indirectly reflected the severity of disease. Those patients for whom a portable chest radiograph was done, for those whom the lung ultrasonogram was done in the supine position and patients who were intubated or receiving non-invasive ventilation were considered to be sicker.

DIAGNOSTIC ACCURACY OF LUS (Lung ultrasonogram)

The primary objective of the study was to study the sensitivity and specificity of lung ultrasonogram compared to a composite reference standard. At baseline, 211 (65.73%) patients had a respiratory or cardiac condition based on the composite reference standard. A respiratory condition was correctly diagnosed in 174 of the 211 patients with a confirmed respiratory condition. This resulted in a sensitivity of 82.5% [95% CI, 76.50-87.20]. No signs of a respiratory condition were found in 37 of the patients resulting in a specificity of 78.2% [95% CI, 69.09-85.26]. The likelihood ratio for

negative and positive lung ultrasonogram findings were 0.22 [95% CI, 0.16-0.31] and 3.78 [95% CI, 2.64-5.41] respectively.

Table 4 Cross tabulation of LUS and CRS for all lung pathologies [LUS –Lung ultrasonogram, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
LUS positive	174	24	198
LUS negative	37	86	123
Total	211	110	321

This was plotted on Fagan's normogram for likelihood ratios and positive lung ultrasonogram increased the pre-test probability of 66% to a post-test probability of 87% of having lung pathology. In converse, it decreased the pre-test probability from 65% to 30% of not having lung pathology if negative.

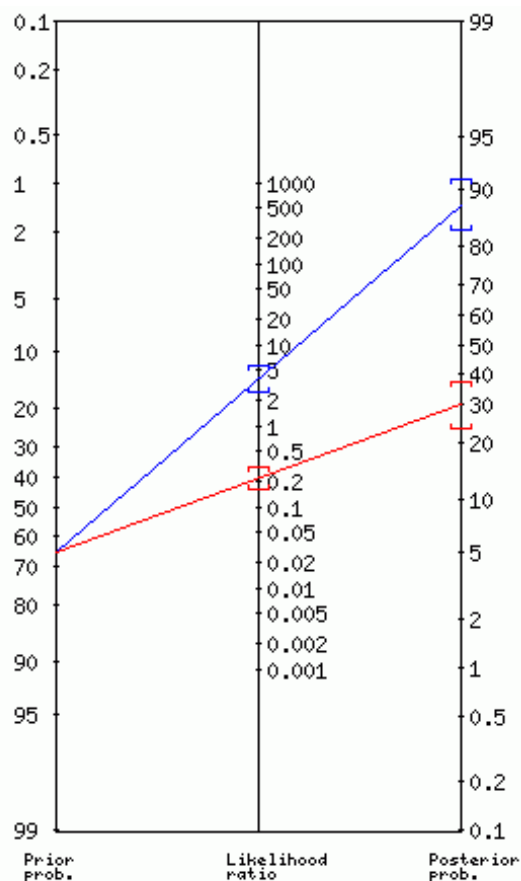


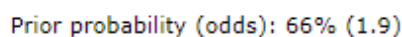
Figure 18 Fagan's normogram showing pre and post-test probability for lung ultrasonogram in detecting any lung pathology

In comparison with lung ultrasonogram, chest radiograph revealed 168 positive and 43 negative studies in patients with a respiratory pathology as determined by the composite reference standard. In comparing ultrasonogram to chest radiograph, 22 cases detected by LUS were missed by the chest radiograph and the chest radiograph picked up 16 cases that were missed by the lung ultrasonogram. This resulted in a sensitivity of 79.6% [95% CI, 73.42-84.71] and a specificity of 86.4% [95% CI, 78.19-91.91]. The likelihood ratio for negative and positive chest radiograph findings were 0.24 [95% CI, 0.18-0.31] and 5.84 [95% CI, 3.63-9.39] respectively.

Table 5 Cross tabulation of CXR and CRS for all lung pathologies [CXR – Chest X-Ray, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
CXR positive	168	15	183
CXR negative	43	95	138
Total	211	110	321

This was plotted on Fagan's normogram for likelihood ratios and chest radiograph increased the pre-test probability of 66% to a post-test probability of 90% of having a lung pathology. In converse, it decreased the pre-test probability from 65% to 30% of not having a lung pathology.



The secondary objective was to assess the diagnostic accuracy of a post graduate resident in using lung ultrasonography to correctly diagnose various pathological conditions compared to a trained faculty. This was estimated by calculating a kappa co-efficient which showed an agreement of 0.77 [95% CI, 0.34-1] which signified substantial agreement.

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was inferior to the kappa co-efficient of the lung ultrasonogram. This shows that only minimal training is required for an adequate interpretation of lung ultrasonography.

Table 6 Kappa between resident and radiologist in interpreting CXR [CXR – Chest X-ray as interpreted by the resident, RCXR – Chest X-ray as interpreted by the radiologist, ARDS – Acute respiratory distress syndrome]

Pathology	CXR	RCXR+	RCXR-	Kappa co-efficient
All lung pathology	CXR+	169	53	0.56 [0.46-0.65]
	CXR -	14	85	
Pleural effusion	CXR+	87	19	0.63 [0.54-0.72]
	CXR-	35	180	
Pneumonia	CXR+	48	48	0.33 [0.21-0.45]
	CXR-	39	186	
Pulmonary edema	CXR+	13	31	0.32 [0.13-0.51]
	CXR-	10	267	
ARDS	CXR+	6	16	0.36 [0.08-0.64]
	CXR-	3	296	

ADDITIONAL RESULTS

Sub-group analysis was done with sensitivity and specificity carried out for the different pathologies separately.

PLEURAL EFFUSION

Pleural effusion was correctly diagnosed in 62 of 71 patients with a confirmed effusion. This resulted in a sensitivity of 83.8% [95% CI, 72.99-90.98]. No features of a pleural effusion were found in 74 of 130 patients resulting in a specificity of 56.9% [95% CI, 47.95-65.48]. The likelihood ratio for negative and positive lung ultrasonogram findings for effusion were 0.28 [95% CI, 0.17-0.49] and 1.94 [95% CI, 1.56-2.43].

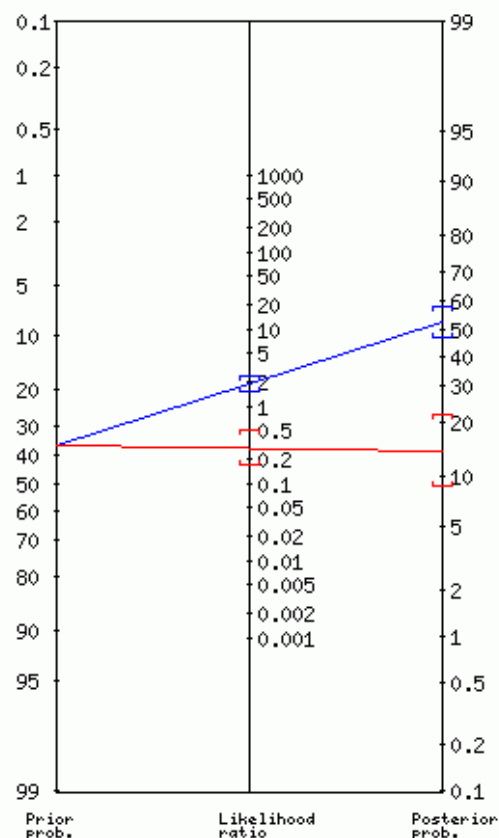
Table 7 Cross tabulation of LUS and CRS for effusion [LUS – Lung ultrasonogram, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
LUS positive	62	56	118
LUS negative	12	74	83
Total	74	130	321



Figure 20 Pleural effusion

This was plotted on Fagan's normogram for likelihood ratios and lung ultrasonogram increased the pre-test probability of 36% to a post-test probability of 52% of having a pleural effusion. In converse, it decreased the pre-test probability from 36% to 15% of not having a pleural effusion.



Prior probability (odds): 36% (0.6)

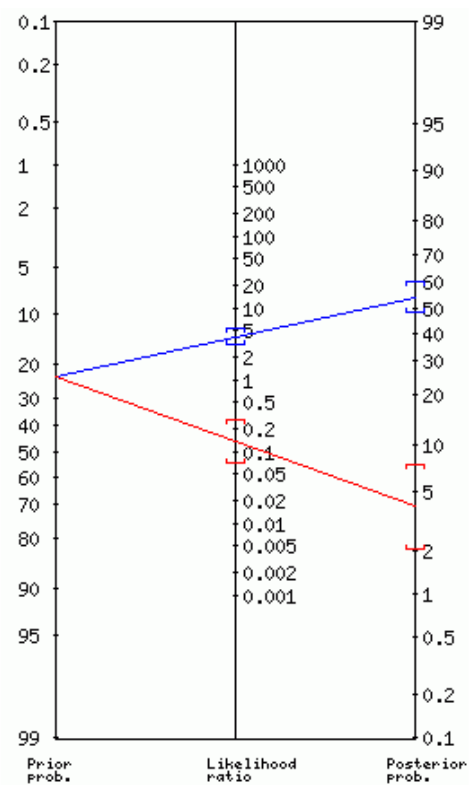
Figure 21 Fagan's normogram showing pre and post-test probability for lung ultrasonogram in detecting pleural effusion

In comparison with lung ultrasonogram, chest radiograph revealed 66 positive and 8 negative studies in patients with a pleural effusion as determined by the composite reference standard. In comparing ultrasonogram to chest radiograph, 56 cases detected by LUS were missed by the chest radiograph and the chest radiograph picked up 10 cases that were missed by the lung ultrasonogram. This resulted in a sensitivity of 89.2% [95% CI, 79.27-94.88] and a specificity of 77.3% [95% CI, 71.49-82.29]. The likelihood ratio for negative and positive chest radiograph findings were 0.14 [95% CI, 0.07-0.27] and 3.93 [95% CI, 3.08-5.02] respectively.

Table 8 Cross tabulation of CXR and CRS for effusion [CXR – Chest X-Ray, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
CXR positive	66	56	122
CXR negative	8	191	199
Total	74	247	321

This was plotted on Fagan's nomogram for likelihood ratios and chest radiograph increased the pre-test probability of 23% to a post-test probability of 55% of having a pleural effusion. In converse, it decreased the pre-test probability from 23% to 4% of not having a pleural effusion.



Prior probability (odds): 23% (0.3)

Figure 22 Fagan's normogram showing pre and post-test probability for chest X-ray in detecting pleural effusion



Figure 23 Chest radiograph showing right sided pleural effusion

PNEUMONIA

Consolidation/ pneumonia was correctly diagnosed in 66 of 97 patients with a confirmed pneumonia. This resulted in a sensitivity of 68% [95% CI, 57.69-76.93]. No features of pneumonia were found in 184 of 224 patients resulting in a specificity of 82.1% [95% CI, 76.35-86.79]. The likelihood ratio for negative and positive lung ultrasonogram findings for pneumonia were 0.39 [95% CI, 0.29-0.52] and 3.81 [95% CI, 2.79-5.21].

Table 9 Cross tabulation of LUS and CRS for pneumonia [LUS – Lung ultrasonogram, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
LUS positive	66	40	106
LUS negative	31	184	215
Total	97	224	321

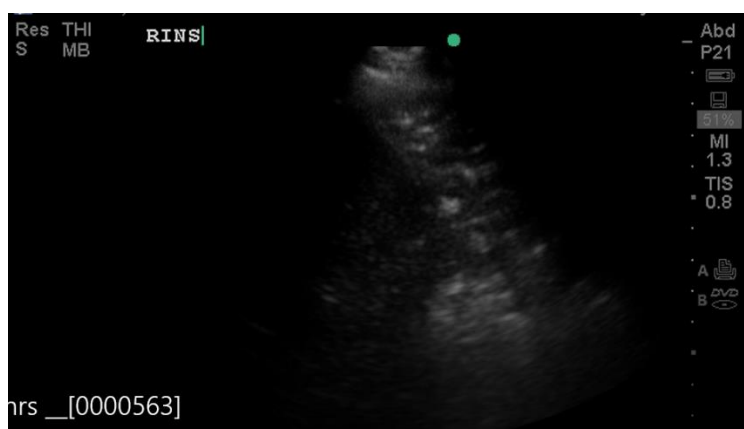


Figure 24 Consolidation as seen on lung ultrasound

This was plotted on Fagan's normogram for likelihood ratios and lung ultrasonogram increased the pre-test probability of 30% to a post-test probability of 62% of having a pneumonia. In converse, it decreased the pre-test probability from 30% to 15% of not having a pneumonia.

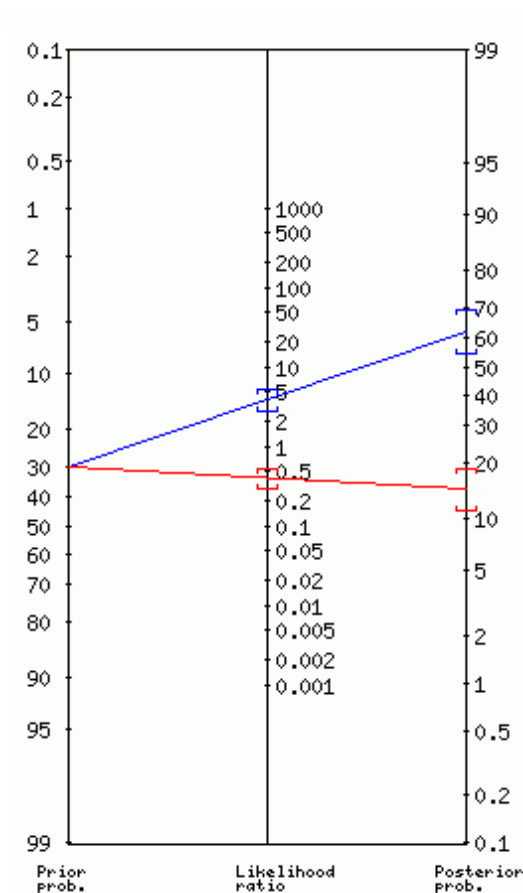


Figure 25 Fagan's normogram showing pre and post-test probability for lung ultrasonogram in detecting pneumonia

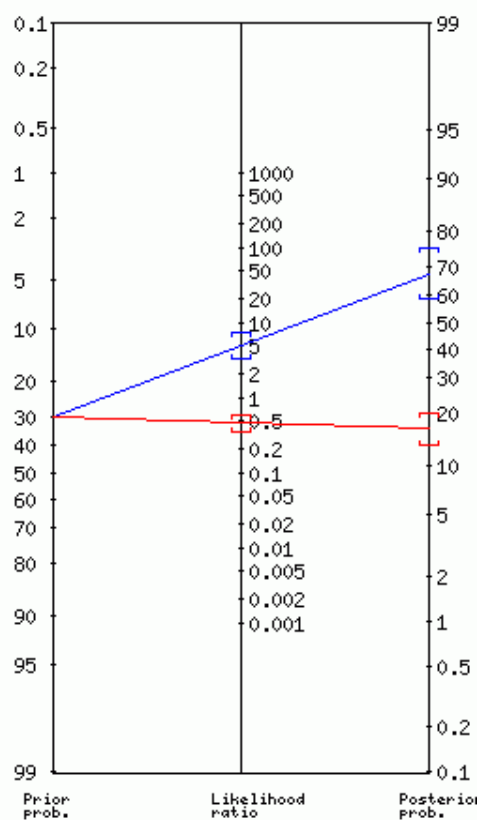
In comparison with lung ultrasonogram, chest radiograph revealed 59 positive and 38 negative studies in patients with a consolidation as determined by the composite

reference standard. In comparing ultrasonogram to chest radiograph, 10 cases detected by LUS were missed by the chest radiograph and the chest radiograph picked up 8 cases that were missed by the lung ultrasonogram. This resulted in a sensitivity of 60.8% [95% CI, 50.35-70.42] and a specificity of 87.5% [95% CI, 82.27-91.39]. The likelihood ratio for negative and positive chest radiograph findings were 0.45 [95% CI, 0.35-0.58] and 4.87 [95% CI, 3.32-7.13] respectively.

Table 10 Cross tabulation of CXR and CRS for pneumonia [CXR – Chest X-Ray, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
CXR positive	59	28	87
CXR negative	38	196	234
Total	97	224	321

This was plotted on Fagan's normogram for likelihood ratios and chest radiograph increased the pre-test probability of 30% to a post-test probability of 68% of having a pneumonia. In converse, it decreased the pre-test probability from 30% to 17% of not having a pneumonia.



Prior probability (odds): 30% (0.4)

Figure 26 Fagan's normogram showing pre and post-test probability for chest X-ray in detecting pneumonia



Figure 27 Chest X-ray showing right upper lobe consolidation

Out of the 97 patients diagnosed to have a pneumonia, 13 of these patients had a final diagnosis of an interstitial pneumonia. Only one of these cases were picked up by the lung ultrasonogram and chest radiograph.

PULMONARY EDEMA

Pulmonary edema was correctly diagnosed in 25 of 53 patients with a confirmed diagnosis of pulmonary edema. This resulted in a sensitivity of 47.2% [95% CI, 33.51-61.23]. No features of pulmonary edema were found in 260 of 268 patients resulting in a specificity of 97% [95% CI, 93.98-98.60]. The likelihood ratio for negative and positive lung ultrasonogram findings for pulmonary edema were 0.54 [95% CI, 0.42-0.70] and 16 [95% CI, 7.54-33].

Table 11 Cross tabulation of LUS and CRS for pulmonary edema [LUS – Lung ultrasonogram, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
LUS positive	25	8	33
LUS negative	28	260	288
Total	53	268	321

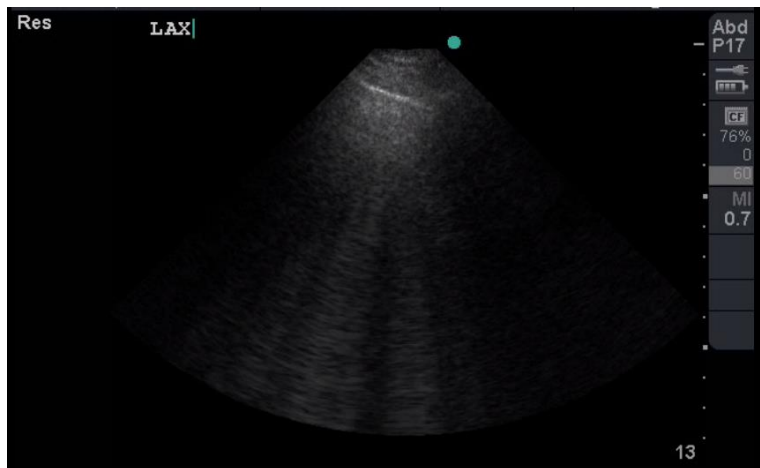
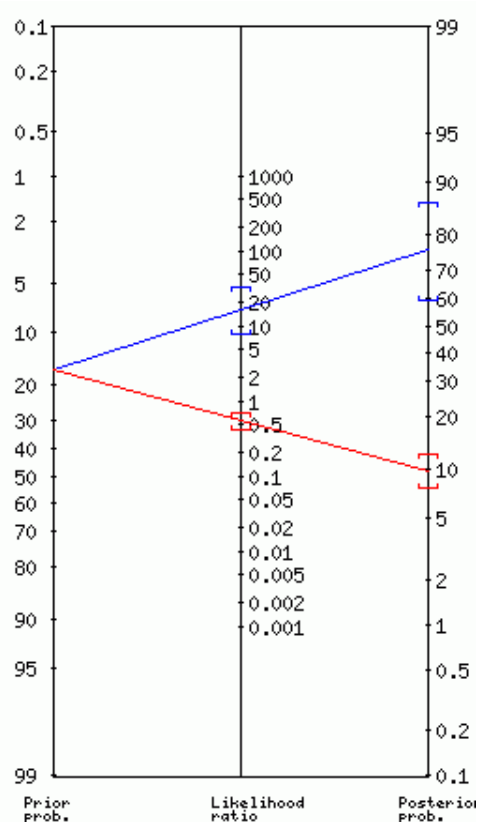


Figure 28 Pulmonary edema

This was plotted on Fagan's normogram for likelihood ratios and lung ultrasonogram increased the pre-test probability of 17% to a post-test probability of 75% of having pulmonary edema. In converse, it decreased the pre-test probability from 17% to 10% of not having pulmonary edema.



Prior probability (odds): 17% (0.2)

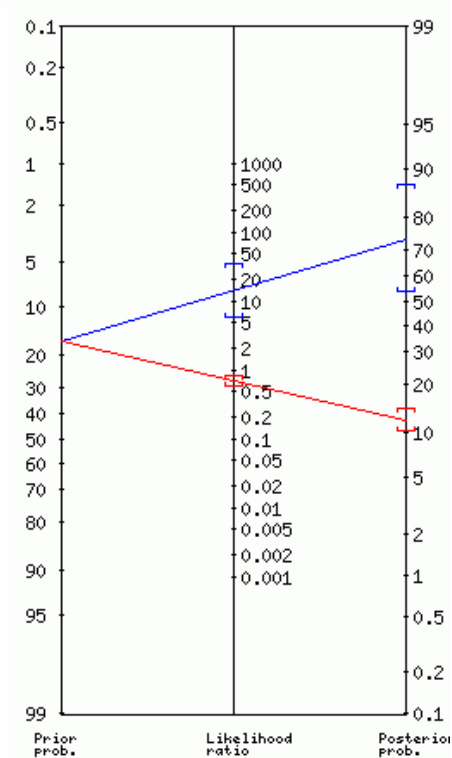
Figure 29 Fagan's normogram showing pre and post-test probability for lung ultrasonogram in detecting pulmonary edema

In comparison with lung ultrasonogram, chest radiograph revealed 17 positive and 36 negative studies in patients with pulmonary edema as determined by the composite reference standard. In comparing ultrasonogram to chest radiograph, 14 cases detected by LUS were missed by the chest radiograph and the chest radiograph picked up 6 cases that were missed by the lung ultrasonogram. This resulted in a sensitivity of 32.1% [95% CI, 20.30-46.44] and a specificity of 97.8% [95% CI, 94.95-99.08]. The likelihood ratio for negative and positive chest radiograph findings were 0.69 [95% CI, 0.58-0.84] and 14 [95% CI, 5.93-35] respectively.

Table 12 Cross tabulation of CXR and CRS for pulmonary edema [CXR – Chest X-Ray, CRS – Composite reference standard]

	Diagnosis positive	Diagnosis negative	Total
CXR positive	17	6	87
CXR negative	36	262	234
Total	23	268	321

This was plotted on Fagan's nomogram for likelihood ratios and chest radiograph increased the pre-test probability of 17% to a post-test probability of 72% of having pulmonary edema. In converse, it decreased the pre-test probability from 17% to 12% of not having pulmonary edema.



Prior probability (odds): 17% (0.2)

Figure 30 Fagan's normogram showing pre and post-test probability for chest X-ray in detecting pulmonary edema



Figure 31 Chest X-ray showing pulmonary edema

ACUTE RESPIRATORY DISTRESS SYNDROME

ARDS was correctly diagnosed in 15 of 22 patients with a confirmed diagnosis of ARDS. This resulted in a sensitivity of 68.2% [95% CI, 45.11-85.26]. No features of ARDS were found in 293 of 299 patients resulting in a specificity of 98% [95% CI, 95.46-99.18]. The likelihood ratio for negative and positive lung ultrasonogram findings for ARDS were 0.32 [95% CI, 0.18-0.60] and 34 [95% CI, 15-79].

Table 13 Cross tabulation of LUS and CRS for ARDS [LUS – Lung ultrasonogram CRS – Composite reference standard, ARDS – Acute respiratory distress syndrome]

	Diagnosis positive	Diagnosis negative	Total
LUS positive	15	6	21
LUS negative	7	293	300
Total	22	299	321

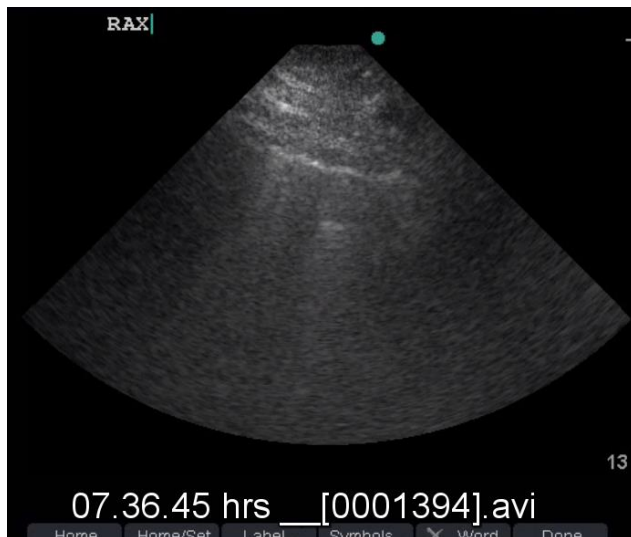
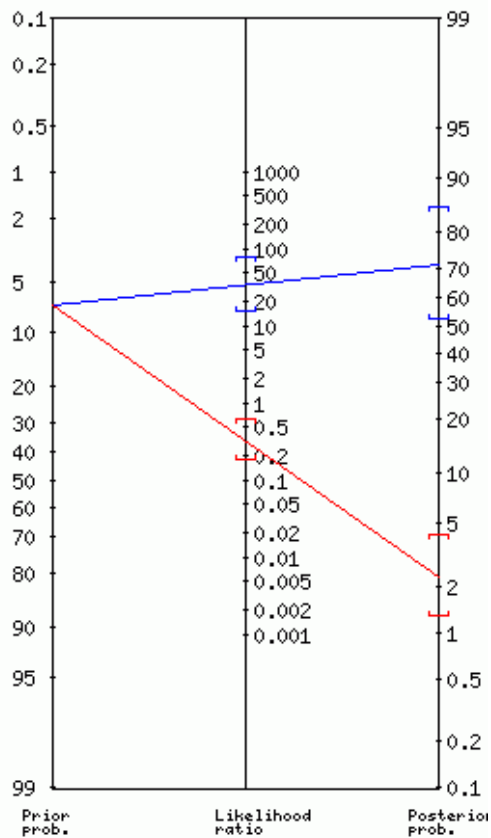


Figure 32 ARDS – Acute respiratory distress syndrome

This was plotted on Fagan's normogram for likelihood ratios and lung ultrasonogram increased the pre-test probability of 7% to a post-test probability of 70% of having ARDS. In converse, it decreased the pre-test probability from 7% to 2% of not having ARDS.



Prior probability (odds): 7% (0.1)

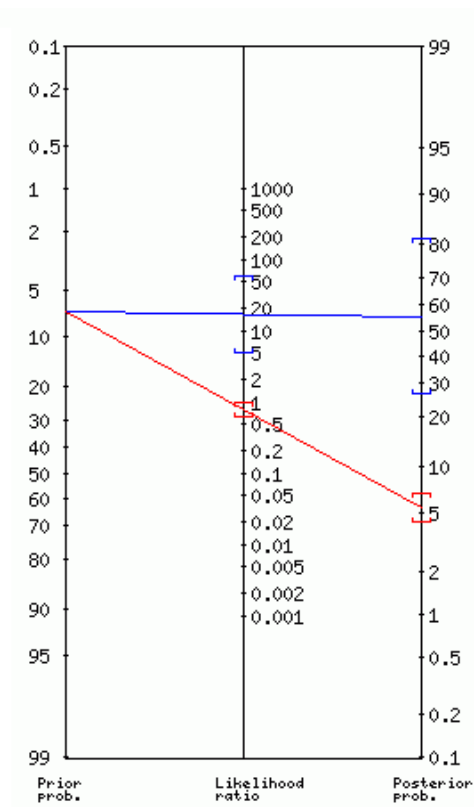
Figure 33 Fagan's normogram showing pre and post-test probability for lung ultrasonogram in detecting acute respiratory distress syndrome

In comparison with lung ultrasonogram, chest radiograph revealed 5 positive and 17 negative studies in patients with ARDS as determined by the composite reference standard. In comparing ultrasonogram to chest radiograph, 10 cases detected by LUS were missed by the chest radiograph but the LUS did not miss any cases that were picked up by chest radiograph. This resulted in a sensitivity of 22.7% [95% CI, 8.68-45.82] and a specificity of 98.7% [95% CI, 96.37-99.57]. The likelihood ratio for negative and positive chest radiograph findings were 0.78 [95% CI, 0.62-0.98] and 17 [95% CI, 4.91-59] respectively.

Table 14 Cross tabulation of CXR and CRS for ARDS [CXR – Chest X-Ray, CRS – Composite reference standard, ARDS – Acute respiratory distress syndrome]

	Diagnosis positive	Diagnosis negative	Total
CXR positive	5	4	87
CXR negative	17	295	234
Total	22	299	321

This was plotted on Fagan's nomogram for likelihood ratios and chest radiograph increased the pre-test probability of 7% to a post-test probability of 55% of having ARDS. In converse, it decreased the pre-test probability from 7% to 5% of not having ARDS.



Prior probability (odds): 7% (0.1)

Figure 34 Fagan's nomogram showing pre and post-test probability for chest X-ray in detecting acute respiratory distress syndrome

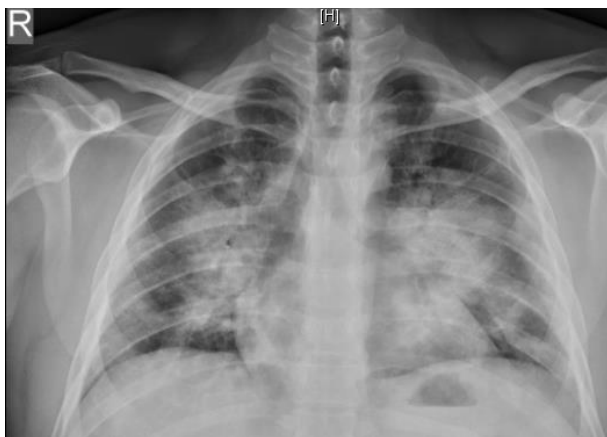


Figure 35 Chest radiograph showing features suggestive of acute respiratory distress syndrome

PNEUMOTHORAX

There was only one case of pneumothorax which was picked up by both LUS and the chest radiograph. The chest radiograph picked up one extra pneumothorax that was negative on the LUS study and by the composite reference standard.

OTHER CONDITIONS

Miliary mottling, hilar lymphadenopathy, mediastinal widening and presence of a lung mass or nodule was also recorded. There were three cases of military mottling, two of which were picked up by the LUS and one was picked up by the chest radiograph.

There were 3 cases of hilar lymphadenopathy that was identified on chest radiograph. However, this was not confirmed by the composite reference standard.

One patient had mediastinal widening, which was picked up on chest radiograph and was not appreciable on LUS. Two extra cases were picked up on chest radiograph which were not confirmed by the composite reference standard.

6 patients had a lung mass as the final diagnosis, 5 of which were picked up by chest radiograph and only 2 by LUS.

Other conditions besides the ones described above included lung fibrosis (1), which was not picked up by LUS or chest radiograph.

Chronic obstructive pulmonary disease (COPD) was found in 9 patients, one of which was identified on LUS. However, chest radiograph picked up 8 cases of COPD.

7 cases of pulmonary arterial hypertension was diagnosed on chest radiograph, however neither the composite reference standard of LUS identified PAH as a pathology.

Bronchiectasis was the final diagnosis in 7 cases, 5 of which were picked up by chest radiograph and only two by LUS.

4 patients were diagnosed to have interstitial lung disease. Chest radiograph diagnosed two of these cases correctly and LUS did not identify any.

The above results are summarised in Table 15.

Table 15 Summary of results [LR – Likelihood ratio, ARDS – Acute respiratory distress syndrome]

Pathology	Sensitivity	Specificity	Positive LR	Negative LR
All lung pathologies	82.5	78.2	3.78	0.22
Pleural effusion	83.8	56.9	1.94	0.28
Consolidation	68	82.1	3.81	0.39
Pulmonary edema	47.2	97	16	0.54
ARDS	68.2	98	34	0.32

LUNG ULTRASOUND AS PART OF THE COMPOSITE REFERENCE STANDARD

In the first 54 patients included in the study, the lung ultrasonogram result was also provided to the physician functioning as the composite reference standard. A separate analysis was done to see if sensitivity and specificity changed.

Table 16 Summary of all conditions when LUS was part of CRS (N=54) [LUS – Lung ultrasonogram, CRS – Composite reference standard, ARDS – Acute respiratory distress syndrome, PLR – Positive likelihood ratio, NLR – Negative likelihood ratio]

Pathology	LUS	CRS +	CRS -	Sensitivity	Specificity	PLR	NLR
All lung pathology	LUS+	29	4	87.9	81	4.61	0.15 [0.06-
	LUS -	4	17			[1.89-11]	0.38]
Pleural effusion	LUS+	11	3	78.6	92.5	10 [3.41-	0.23 [0.08-
	LUS-	3	37			32]	0.63]
Pneumonia	LUS+	13	13	86.7	66.7	2.60	0.20 [0.05-
	LUS-	2	26			[1.60-4.23]	0.74]
Pulmonary edema	LUS+	5	1	100	98	49 [6.20-	0 [0.01-1.22]
	LUS-	0	48			151]	
ARDS	LUS+	4	2	80	95.9	20 [4.71-	0.21 [0.04-
	LUS-	1	47			82]	1.20]

Table 17 Summary of all conditions when LUS was not part of CRS (N=267) [LUS – Lung ultrasonogram, CRS – Composite reference standard, ARDS – Acute respiratory distress syndrome, PLR – Positive likelihood ratio, NLR – Negative likelihood ratio]

Pathology	LUS	CRS +	CRS -	Sensitivity	Specificity	PLR	NLR
All lung pathology	LUS+	145	20	81.5	77.5	3.62 [2.45-5.37]	0.24 [0.17-0.33]
	LUS -	33	69				
Pleural effusion	LUS+	51	53	85	74.4	3.32 [2.57-4.29]	0.20 [0.11-0.37]
	LUS-	9	154				
Pneumonia	LUS+	53	27	64.6	85.4	4.43 [3.02-6.50]	0.41 [0.31-0.56]
	LUS-	29	158				
Pulmonary edema	LUS+	20	7	41.7	96.8	13 [5.85-29]	0.60 [0.47-0.77]
	LUS-	28	212				
ARDS	LUS+	11	4	64.7	98.4	40 [14-114]	0.36 [0.19-0.68]
	LUS-	6	246				

COMPUTED TOMOGRAPHY AS PART OF THE COMPOSITE REFERENCE STANDARD

A sub-group analysis of the patients in whom a CT was also done and was part of the reference standard was done. The results show that the sensitivity and specificity of the lung ultrasonogram increased when the CT was included.

Table 18 Summary of all conditions when CT (N= 80) was done [LUS – Lung ultrasonogram, CRS – Composite reference standard, ARDS – Acute respiratory distress syndrome, PLR – Positive likelihood ratio, NLR – Negative likelihood ratio]

Pathology	LUS	CRS +	CRS -	Sensitivity	Specificity	PLR	NLR
All lung pathology	LUS+	58	1	87.9	92.9	12 [1.86-82]	0.13 [0.07-0.25]
	LUS -	8	13				
Pleural effusion	LUS+	31	5	81.6	88.1	6.85 [2.97-16]	0.21 [0.11-0.41]
	LUS-	7	37				
Pneumonia	LUS+	31	4	75.6	89.7	7.37 [2.87-19]	0.27 [0.16-0.47]
	LUS-	10	35				
Pulmonary edema	LUS+	4	2	100	97.4	38 [7.91-97]	0 [0.01-1.43]
	LUS-	0	74				
ARDS	LUS+	0	2	100	97.4	38	-
	LUS-	0	78				

OTHER ANALYSIS

Other factors such as duration of illness, position of the patient during lung ultrasonogram, whether a portable or regular chest radiograph was done and whether patient was ventilated or not were also taken into consideration and separate subgroup analysis was done for each group.

Table 19 Summary of all conditions when symptoms were less than 1 day (N=36) [LUS – Lung ultrasonogram, CRS – Composite reference standard, ARDS – Acute respiratory distress syndrome, PLR – Positive likelihood ratio, NLR – Negative likelihood ratio]

Pathology	LUS	CRS +	CRS -	Sensitivity	Specificity	PLR	NLR
All lung pathology	LUS+	9	7	81.8	72	2.92 [1.47-5.81]	0.25 [0.07-0.91]
	LUS -	2	18				
Pleural effusion	LUS+	4	8	100	75	4 [1.83-6.68]	0.00 [0.01-1.88]
	LUS-	0	24				
Pneumonia	LUS+	1	5	33.3	84.8	2.20 [0.37-13]	0.79 [0.35-1.77]
	LUS-	2	28				
Pulmonary edema	LUS+	1	0	25	100	Infinity	0.75 [0.40-1.26]
	LUS-	3	32				
ARDS	LUS+	0	1	25	100	0	0
	LUS-	0	35				

Table 20 Summary of all conditions when chest radiograph was portable (N= 71) [LUS – Lung ultrasonogram, CRS – Composite reference standard, ARDS – Acute respiratory distress syndrome, PLR – Positive likelihood ratio, NLR – Negative likelihood ratio]

Pathology	LUS	CRS +	CRS -	Sensitivity	Specificity	PLR	NLR
All lung pathology	LUS+	48	3	92.3	84.2	5.85 [2.06-17]	0.09 [0.03-0.24]
	LUS -	4	16				
Pleural effusion	LUS+	15	16	78.9	69.2	2.57 [1.60-4.10]	0.30 [0.12-0.74]
	LUS-	4	36				
Pneumonia	LUS+	12	15	92.3	74.1	3.57 [2.25-5.67]	0.10 [0.02-0.69]
	LUS-	1	43				
Pulmonary edema	LUS+	9	0	42.9	100	Infinity	0.57 [0.40-0.83]
	LUS-	12	50				
ARDS	LUS+	8	3	88.9	95.2	18 [5.95-57]	0.12 [0.02-0.74]
	LUS-	1	59				

The average time taken for a LUS was around 10 minutes and if patient was ventilated and required assistance in changing position, around 15 minutes was taken. On the other hand, the average time lapse between a resident ordering a CXR and it getting done was around 2 hours and could be as long as 12 hours.

There were no side effects associated with the use of the lung ultrasonogram.

DISCUSSION

Lung diseases are common conditions in general medical wards. Some primarily affect the lung, like pneumonias while others are the effect of other organ pathologies such as pulmonary edema secondary to cardiac disease. With increasing complexity of patients with multi-morbidities, clinical findings often need augmentation with laboratory investigations such as chest X-rays or CT scans. It is in this context that we studied the role of ultrasonogram in chest or lung diseases in India.

The population that was included in the study were admitted in the general medical ward and hence, consisted of a majority of stable patients with no hemodynamic instability. It included predominantly a middle aged population with a mean age of 49 years with more males than females. These patients had commonly occurring co-morbid conditions such as diabetes (34.2%) and hypertension (28.9%), and obstructive airway disease (6.23%)

Only patients who had respiratory or cardiac complaints or examination findings suggestive of a cardiac or respiratory pathology were included in the study as this would mimic actual clinical practice where a lung ultrasound would be ordered.

Our study showed that lung ultrasonogram had an overall a sensitivity of 83%, specificity of 78% and positive and negative likelihood ratio of 3.78 and 0.22 respectively for all lung pathologies. The chest radiograph in comparison had a

sensitivity of 80 %, specificity of 86% and positive and negative likelihood ratios of 5.84 and 0.24.

This sensitivity and specificity is comparable to other large studies that have been carried out in a sicker population subset. The largest of these is the study carried out by Lichtenstein et al, which included a total of 260 patients. The sensitivity and specificity were studied separately for different pathologies. It was found to be 97% sensitive and 95% specific for pulmonary edema, 89% sensitive and 94% specific for pneumonia and showed 81% sensitivity and 100% specificity for pneumothorax.(5) Meta- analysis for the different pathologies show a sensitivity and specificity of 85% and 93%, respectively, for pneumonia, (62), 94% and 98%, respectively, for effusion, (27), and 94% and 92%, respectively, for pulmonary edema. (77) A meta-analysis published in 2017, showed that the sensitivity varied from 57 – 100% and the specificity from 54-99% for the diagnosis of pneumonia. (96)

A sub-group analysis where computed tomography (CT) was part of the composite reference standard showed that the sensitivity increased to around 88% and a specificity that increased to around 93%. This led us to an inference that the CT picked up lung pathologies that were present but were not clinically significant, which is why a positive LUS / CT would have been labelled as normal when assessed by the composite reference standard. This was particularly evident in the case of pleural effusion. When the reference was the composite reference standard, the specificity of LUS was low (56.9%), however, when CT was part of the standard, the specificity

dramatically increased (88.1%), indicating that the LUS like the CT picks up effusions that may or not be clinically significant. Hence, there was good co-relation between LUS and CT findings. Hence, in patients that required lung imaging and CT could not be done for any reason, LUS is a good alternative.

Sub- group analysis was done for the different pathologies commonly seen (pleural effusion, consolidation, pulmonary edema and ARDS). It was found that there was superior sensitivity and specificity of LUS compared to CXR in all these different pathologies particularly in pulmonary edema and ARDS.

In effusions, when compared to a recent meta-analysis which took CT as a gold standard, our sensitivity and specificity was low. However, when comparing the sensitivity and specificity of our CT subset of patients, the values were comparable.(27)

On comparing patients with pulmonary edema, our sensitivity and specificity was significantly higher than the prior studies.(77) In the diagnosis of pulmonary edema and ARDS, LUS was found to be very useful for early diagnosis and initiation of early appropriate therapy. Sensitivity was not as high as expected and hence, in these conditions, there will be probable benefit or re-screening at regular intervals.

Multiple prior studies have been done which show that LUS is capable of picking up lung pathologies earlier during the onset of illness in view of delay of appearance of chest radiograph findings.(97) However, in our study, sensitivity and specificity did

not change if duration of illness was less than a day. This may lead us to the inference that more than a day may be required to develop significant chest findings that could be picked up by lung ultrasonogram that point to a particular diagnosis.

It was impractical to calculate scores such as APACHE/ PSI / CURB-65 for the various lung pathologies to classify them into different categories of severity. Hence, patients for whom a portable chest radiograph was done as they were too sick to be shifted for a regular radiograph were considered sick. A sub- group analysis done showed that in the subset of patients in whom a portable chest radiograph was done, the sensitivity and specificity significantly improved (92% and 84% respectively). This was of particular interest as it was in this subset of patients, that shifting elsewhere for radiograph would be time consuming and risky in view of the unstable clinical condition. This remained true in the sub-group analysis of the separate lung pathologies as well. With such high sensitivity and specificity, can we do away with the chest radiograph in this subset of patients? Perhaps more similar studies are required in a non-ICU setting.

Other pathologies such as mediastinal widening, hilar lymphadenopathy, interstitial lung disease, bronchiectasis, COPD and pulmonary artery hypertension were not picked up by the LUS. This must be kept in mind when interpreting a LUS as most interstitial and mediastinal pathologies are missed with this modality.

The secondary objective of our study was to calculate a kappa co-efficient between the principal investigator and the expert in lung ultrasonogram. Only minimal training was carried out prior to the study (of around 1 hour) after which a kappa was calculated. The Kappa value was 0.77 which signified substantial agreement. This suggests that lung ultrasound could be taught by experts to general medicine post-graduates and faculty in a short span in a proper manner.

However, on comparison of the kappa between the internal medicine residents and the radiologist in interpreting the chest radiograph, the value was found to be low (0.56) signifying high inter-observer variability. This showed that more training was required to correctly interpret a radiograph especially a portable CXR.

The other advantages that the LUS has over the chest radiograph was the time saved and that the patient did not have to be shifted anywhere for a chest radiograph. The average time taken for a LUS was around 10 minutes and if patient was ventilated and required assistance in changing position, around 15 minutes was taken. On the other hand, the average time lapse between a resident ordering a CXR and it getting done was around 2 hours and could be as long as 12 hours. The cost of a chest radiograph is Rs.195/- compared to Rs.820/- for a LUS. A CT Thorax with contrast costs Rs.7200/-. This cost could be avoided in certain patients if a bedside LUS could be done to arrive at a diagnosis. The LUS was also found to be a useful bedside tool for guided pleural fluid aspiration.

LIMITATIONS

We made every effort to follow the current STARD guidelines for diagnostic tests to minimize bias.

As our reference standard was a composite reference standard, it picked up only clinically significant pathologies. It did not merely determine absence or presence which resulted in several pathologies that were picked up the CT being missed by the composite reference standard. Some of the finding that were false positive by the lung ultrasonogram may have been clinically insignificant but still present lung pathologies. The radiologist found that more clinical data and few other investigations were required to make a more accurate diagnosis. The final diagnosis was occasionally different from the point in time when LUS and CXR was done

The rationale of this study was to see if LUS was comparable to CXR in the diagnosis of various lung pathologies in a general medical ward. We found that the LUS was better than chest radiograph and in most cases as good as a CT. It was particularly useful in diagnosis of pulmonary edema and ARDS. This led us to the conclusion that it was necessary to include training in basics of bedside lung ultrasonography in the internal medicine resident syllabus as it has proved to be a useful tool in diagnosis, procedures and initiation of appropriate therapy. Steps should also be taken that a low

cost ultrasound machine be available in medical wards so that clinical diagnosis can be aided with this useful tool.

In a low resource setting like India, where access to chest radiograph and CT may be difficult particularly in a rural set-up, the presence of a LUS machine would be very helpful in easy bedside diagnosis and to save costs on a CT. In addition, very minimal training is required for acquiring images and interpretation of the same.

CONCLUSION

1. The sensitivity, specificity, positive and negative likelihood ratios for lung ultrasound for all lung conditions were 82%, 78%, 3.78 and 0.22, respectively, as compared to a composite reference standard
2. Among patients with CT scan included as a composite reference standard the sensitivity, specificity, positive and negative likelihood ratios for lung ultrasound for all lung conditions were 88%, 93%, 12 and 0.13, respectively.
3. For patients with pulmonary edema the sensitivity, specificity, positive and negative likelihood ratios were 47%, 97%, 16 and 0.54, respectively.

4. The agreement between the investigator (resident) and the expert in lung ultrasonogram was 77% (kappa), with a small but reasonable amount of training.
5. The time taken for Ultrasound chest was an average of 10 minutes.
6. The cost of lung ultrasound in our institution was INR 820 as compared with a CT Thorax of INR 7200.

Our study shows that the sensitivity and specificity of the bedside lung ultrasonogram is better than the chest radiograph and in most pathologies, is as good as a computed tomograph of the chest. It required minimal training and only an average of 10 minutes were taken to do the entire scan. It is also more affordable than a CT of the chest.

It would be a useful step to include training in basics of bedside lung ultrasonography in the internal medicine resident syllabus as it has proved to be a useful tool in diagnosis, procedures and initiation of appropriate therapy. Steps should also be taken that a low cost ultrasound machine be available in medical wards so that clinical diagnosis can be aided with this useful tool.

In a low resource setting like India, where access to chest radiograph and CT may be difficult, particularly in a rural set-up, the presence of a LUS machine would be very helpful in easy bedside diagnosis and to save cost on a CT. In addition, very minimal training is required for acquiring images and interpretation of the same.

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ANNEXURES

ANNEXURE 1 -BASICS OF ULTRASOUND

FREQUENCY

Ultrasound waves refer to high frequency sound waves that are used in the field of medicine to delineate different medical conditions on the basis of the penetrating power. (98) The waves are measured in Hertz and is defined as 1 wave per second. In medicine, the ultrasound used is in the range of 2-15 MHz.(99)

The lower the frequency of the sound wave, the higher the penetrating power and hence deeper the images that can be viewed.

SOUND WAVES IN THE HUMAN BODY

As these sound waves travel in the human body, some are scattered, some are transmitted and some are refracted. The further the sound waves go, the weaker it gets and the less is seen on the screen.

To form an image on the screen, the sound waves need to bounce on a surface and get reflected to the probe. This reflection usually takes place at the borders between organs and tissues because each tissue/organ has a different impedance to the sound wave.

Fluid filled structures allow the sound waves to pass very easily through them and hence do not reflect any rays back to the probe. Hence, fluid filled structures appear dark or anechoic.

On the other hand, when these waves hit air, they are scattered in all directions and most of these waves return to the probe making air look very bright. (48)

FORMATION OF SOUND WAVES AND IMAGES

Piezoelectric crystals are encased in a coupling material at the end of the probe. When an electromagnetic wave is passed through this crystal, it vibrates and converts this energy into a sound wave. This sound wave then penetrates the tissues and when it encounters an obstruction, it bounces back and is received by the piezoelectric crystal which converts this back to an electric signal.(10)

This electric signal is then plotted on a screen based on the speed at which the wave returns and the strength of the returning echoes. The quicker the wave bounced back is represented by images closer to the top of the screen. The echoes are stronger when they bounce off a very reflective surface such as bone, and hence, the images on the screen will be brighter. (99)

ULTRASOUND APPEARANCE OF TISSUES

ANECHOIC

Fluid such as blood, urine and bile do not reflect any waves and hence appear black. They also make deeper structures appear brighter in a phenomenon called posterior acoustic enhancement.



Figure 36 Pleural Effusion

ECHOGENIC/ HYPERECHOIC

Denser structures such as bone reflect more waves and the images look brighter on screen. This is seen in the case of bone and gall stones.(10)

Some structures are grey – liver, spleen, kidney and uterus and reflect only some of the rays.

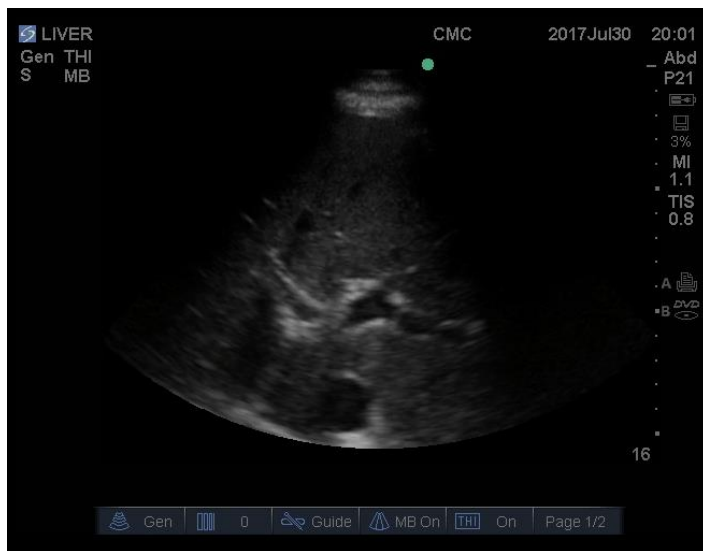


Figure 37 Liver

ARTIFACTS

An artifact is an image that does not correspond to actual anatomic information. It may obscure details or mimic a pathology which could lead to diagnostic uncertainty.

(10) It could also be helpful and forms the basis of lung ultrasonography. Described below are the different types of artifacts.

ACOUSTIC ENHANCEMENT

When sound waves pass through a fluid filled structure, no echoes are reflected and all the waves pass through. However, echoes return to the probe from the deeper structures making them look brighter. This is called acoustic enhancement.(100)

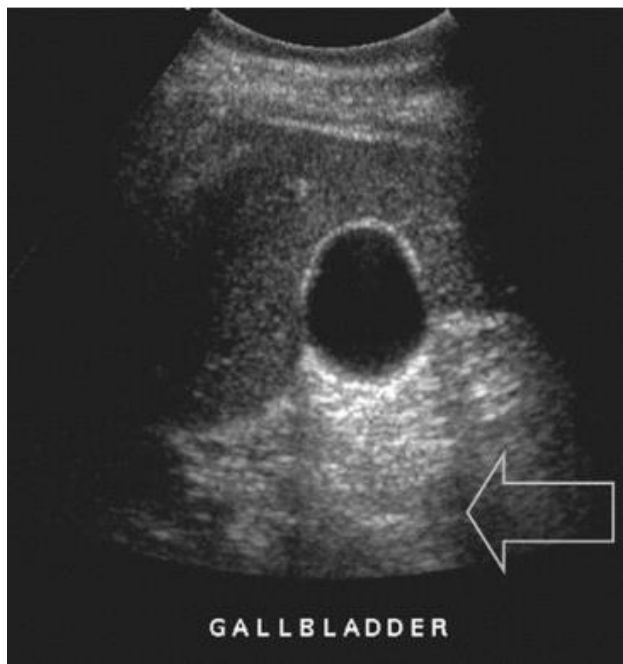


Figure 38 Acoustic Enhancement (Used with permission from Pitchamuthu K. – criticalecho.com)

REVERBERATION

After the sound waves return to the probe after reflection from the tissues, some of them will reflect from the probe and re-enter the body. This process repeats itself and hence a number of images are formed which are serially deeper to the first image.

For example, the second image will be twice as deep as the first image and the third image will be three times as deep as the first image. This results in a series of ghost images deep to the real image. This is called a reverberation artefact.(99) , (100)

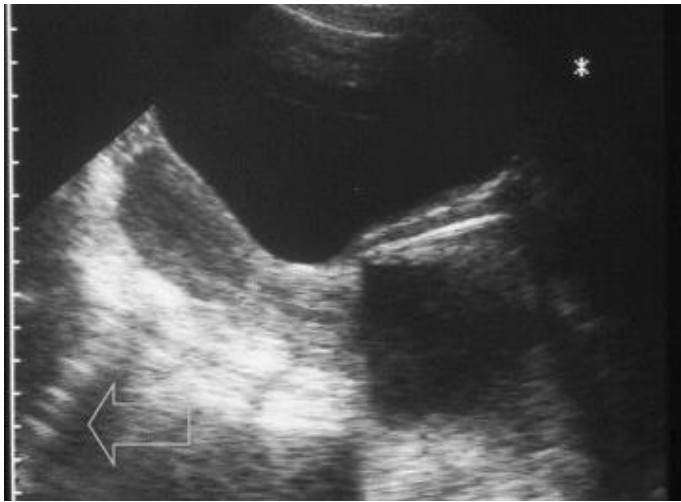


Figure 39 Reverberation artefact (Used with permission from Pitchamuthu K. – criticalecho.com)

MIRROR IMAGE

Certain structures act as mirrors and reflect 100% of the waves and hence, two images of the same structure can form - a true image and a mirror image.

For example – the air in the lungs above the diaphragm along with the smooth surface of the diaphragm creates a mirror image of the liver/ spleen. The waves reflect from the diaphragm through the liver tissue to the probe and back to the diaphragm. The second time it reflects back to the probe, since 100% of the rays have been reflected, the machine cannot tell that this is the second reflection, hence a second mirror image is formed on the other side of the diaphragm deeper than the first image (as it took longer to reach the probe). (100)

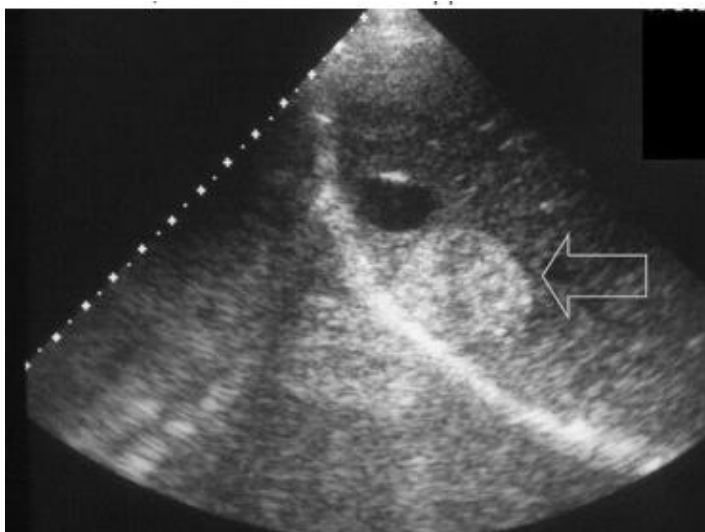


Figure 40 Mirror Image (Used with permission from Pitchamuthu K. – criticalecho.com)

ANNEXURE 2 – BLUE PROTOCOL

The BLUE-protocol was developed based on the study of 300 consecutive adults with acute respiratory failure who were admitted in ICU and given a diagnosis. The gold standard taken was the final diagnosis made by the ICU team. The development of the protocol and sensitivity and specificity of lung ultrasound was calculated in this study.

(16)

In this protocol, there were three points on each hemi-thorax that had to be studied to arrive at a diagnosis. However, this study was carried out on a population that included critically ill individuals in the ICU. Hence, the protocol was designed to be quick and have a high pick up rate for conditions commonly occurring in an ICU setup.

In the BLUE protocol, six points are taken (3 on each hemi-thorax) to complete the study. The points are as follows:

Two hands (from roughly the patient's size) are applied as follows: upper little finger just below clavicle, fingertips at middle line, and lower hand just below upper hand (thumbs excluded). The point coined "upper BLUE-point" is at the middle of the upper hand. The "lower BLUE-point" is at the middle of the lower palm. These four points roughly follow the anatomy of the lung, and avoid the heart as much as possible. The postero-lateral alveolar and/or pleural syndrome (PLAPS)-point is built from the horizontal line continuing the lower BLUE-point and the vertical line continuing the posterior axillary line. This intersection, is called the PLAPS-point.

Like the six spots of ECG, the six BLUE-points help in reproducible analysis. They were sufficient for providing the 90.5% accuracy of the BLUE-protocol.(79)

One feature of the BLUE-protocol is the established profiles, that is, signs associated with locations. These profiles are A-profile, B-profile (hemodynamic pulmonary edema), B'-profile, A/B-profile, C-profile, A-profile without DVT but with posterolateral alveolar and/or pleural syndrome (A-no-V-PLAPS-profile) (pneumonia), A-profile plus DVT (pulmonary embolism), A'-profile (pneumothorax), and nude profile (COPD/asthma).

The A, B, and C profiles were defined as follows:(92)

- A profile (A-lines): white (hyperechoic) horizontal lines that are static and appear at regular intervals.
- B profile (B-lines): hyperechoic vertical artifacts that move in synchrony with the respiratory cycle.
- C profile: consolidation image appearing as a tissue structure containing white points consisting of lung parenchyma.

At the anterior chest wall, lung sliding with predominant A-lines define the A-profile. The A-profile indicates a normal anterior lung surface. Associated with a DVT, it is connected with pulmonary embolism. However, in our study, we do not evaluate the presence of DVT.

Lung sliding with lung rockets define the B-profile and usually indicate hemodynamic pulmonary edema. Anterior lung rockets associated with abolished lung sliding define the B'-profile. Unilateral lung rockets define the A/B-profile. This asymmetry of interstitial signs is also linked to pneumonia.

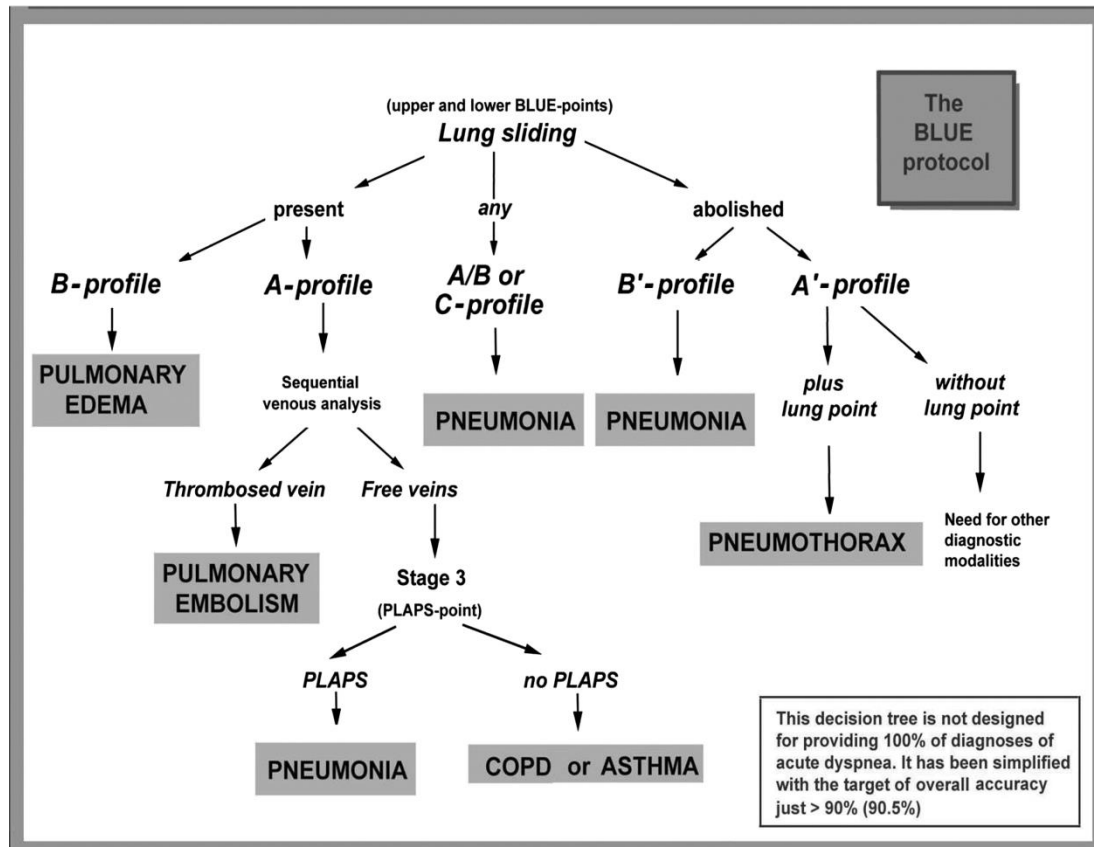
Anterior lung consolidation, regardless of number and size, defines the C-profile. In the BLUE-protocol, the C-profile is associated with pneumonia.

Anterior A-lines associated with abolished lung sliding define the A'-profile. The A'-profile suggests pneumothorax—the lung point is mandatory. In pneumothorax, the abolished lung sliding is explained by the absence of visceral pleura and the A-line by the absence of any fluid structure abutting the parietal pleura. The lung point is explained by the slight inspiratory increase of volume of the collapsed lung and, therefore, an increased parietal contact making an abrupt ultrasound change.

At the posterior chest wall, lung consolidations and pleural effusions are assessed together for simplicity because both disorders usually come together, hence the practical term “PLAPS”. The A-no-V-PLAPS-profile is connected with pneumonia. The A-profile with no DVT and no PLAPS (ie, nude profile) is linked with asthma and COPD.(11)

A summary of the algorithm used is in Table 2.

Table 21 Algorithm for BLUE protocol - Lichenstein et al Chest July 2008 134:117-125



However, in our study, we have not included the DVT screening and hence will only be able to diagnose pulmonary edema, pneumonia, COPD/ Asthma, pleural effusion and pneumothorax.

At the end of the BLUE Protocol study, the sensitivity and specificity of the lung ultrasound was calculated and it was found to be very effective in picking up the various respiratory conditions as shown in Table 3.(11)

Table 22 Sensitiity and specificity of ultrasonogram (Lichenstein et al, CHEST 2015)

Diagnosis	Sensitivity	Specificity
Pulmonary edema	97%	95%
Pneumonia	89%	94%
Pneumothorax	88%	100%
Asthma / COPD	89%	9%

The gold standard taken was the final diagnosis of the treating ICU team which is very similar to our study. This study hopes to reproduce such results.

Studies have also been done to study the difference in pick up rates between a novice and an expert. It has been shown that minimal training in lung ultrasonography is sufficient to pick up lung findings and make an accurate diagnosis.(101), (92)

ANNEXURE 3– INFORMATION AND CONSENT FORM

Information Form for Participants

Study title: Bedside Lung Ultrasonography In A General Medical Ward –
Comparison With Chest Radiography (BLUR)

Study pattern: Diagnostic prospective study

Place of Study: C Ward, Christian Medical College, Vellore

Approximate Number of Subjects: 450

Information sheet

Introduction: You are invited to take part in this research study to determine if a lung ultrasound or a chest X-ray is better at diagnosing common respiratory and cardiac conditions.

Purpose of the research: In people with either respiratory or cardiac complaints, the standard of care includes the use of a chest X-Ray. In this study, we wish to study if a lung ultrasound is as good or better at diagnosing common conditions. If the study

does show that the results of an ultrasound are better, it is possible that that could become the standard of care. The reason a lung ultrasound is being looked at as an alternate option is that it is cheap, safe and can be done by doctors with minimal training. The main advantage is that it is portable and does not expose you to harmful X-Rays. Hence, this study is being carried out to determine if a lung ultrasound is better than a chest X-Ray.

Participant selection: You are being requested to participate/allow your relative to participate in this study as you/he/she have/has been admitted in *C Ward under Medicine Unit 2. The expected duration of the requested participation in this study would be halfan hour (the duration of the ultrasound being done) from the time of admission into the ward, i.e., from the time of entering the study.

Voluntary participation: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, the management and standard of care will remain the same. If you choose not to participate in this research project, you will still continue to receive the same standards of treatment. You may change your mind later and stop participating even if you agreed earlier. This will in no way affect the care that we provide to you.

Information on the research-Procedures & Protocol: We will perform a scan (ultrasound) of your chest within 24 hours of your chest X-Ray being done. Apart

from this we will collect some information on the disease that you suffer from, details of treatment as well as test results to correlate. The scan itself is painless and does not cause any side-effects.

Appropriate Alternate Procedures: Other tests available for detecting pathology in the lungs are more complex scans and include tests like CT Thorax and lung biopsies. However although they may give more information they are more painful and can pose a risk of developing allergy to the dye that is injected, more radiation exposure, bleeding into the chest and leaking of air into the chest. If you need this test for further evaluation, we will talk to you about it.

Risks: There are no risks to doing a scan.

Benefits: The potential benefit is that these scans are not routinely done in patients admitted to the medical wards. If we do find a pathology in the lung, we will inform your treating doctors regarding it.

Reimbursements: You will not be charged for the cost of scan. There are no other incentives. You will not be paid for your participation in the study.

Confidentiality: We will ensure confidentiality of your name and no information that identifies you will be present once we analyze the information and send it for publication.

Sharing of the result: The results of this research is a property of Christian Medical College, Vellore. I am entitled to publish it in a journal or present it in a conference. The participant will have no claim towards the same.

Right to Refuse or Withdraw: You do not have to take part in this research if you do not wish to do so. You may also withdraw participating in the research after giving the consent. It is your choice and all of your rights will be respected.

This proposal has been reviewed and approved by the research and ethics committee of the hospital whose task it is to make sure that research participants are protected from harm.

It has also been reviewed by the Ethics Review Committee CMC Vellore, which is supporting the study.

If there are any further queries regarding this study or regarding the rights of the participants, you can contact me at:

* Ward – C ward under Medicine Unit 2

@ Me/I – Principal Investigator

You – Subject/Participant Date:

Certificate of Consent

Study Title:

Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR)

Subject's Name:

Date of Birth / Age:

Please tick the boxes:

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. []

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. []

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. []

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) []

(v) I agree to take part in the above study. []

Signature (or Thumb impression) of the Subject/ Representative

Signatory's Name:

Date:

Signature of the Investigator:

Study Investigator's Name:

Signature of the Witness:

Name of the Witness:

Date:

ANNEXURE 4 – METHODOLOGY OF POSTERO-ANTERIOR RADIOGRAPHY

METHOD OF POSTERO-ANTERIOR CHEST RADIOGRAPH

These were the general guidelines that were followed for a postero- anterior radiograph.

1. The patient was instructed to sit or stand upright. Patients were positioned to face the film-screen cassette in order to minimize magnification of the anteriorly positioned heart and consequent obscuration of the lungs. The patient was made to stand straight and was equally distributing the weight of the body on both feet.
2. The patient was asked to move the shoulders forward and downward, so that the chest wall and both shoulders were in contact with the cassette. This helps to carry the clavicles below the lung apices.
3. The height of the cassette was adjusted so that its upper border is about 2 inches above the shoulders so that the lung apices are not cut off.
4. The patient was asked to extend the neck, chin, and head upward and vertical.

The neck and chin otherwise tend to superimpose the trachea and uppermost lung regions.

5. The patient's arms were placed overhead or on their hips with elbows angled anteriorly. This will rotate the scapulae off the chest, thereby preventing their superimposition over the lungs.

Central ray

For PA, the chest landmark that is used for locating the center of the lung fields is the *vertebra prominans* (T1). It corresponds to the apical regions of both lungs. The vertebra prominans can be palpated at the base of the neck.

For the average adult, the central ray should be directed to the spinal column (mid-sagittal plane) approximately 7 inches (18 cm) for a female and 8 inches (20 cm) for a male down from the vertebra prominans. This corresponds to the level of T7 and the inferior angle of scapula.

Film holder (image receptor) placement

The horizontal dimension of an average chest is greater than the vertical dimension. This requires that a 14 x 17-inch film holder or image receptor (IR).

Respiration

The exposure was made upon a second full inspiration by the patient. The patient was asked to take as deep a breath as possible, and then hold it to fully aerate the lungs.

Taking a second deep breath before holding it allows for a deeper inspiration, as more air is inhaled during the second breath than during the first breath.

Evaluation criteria for a good PA projection

1. Entire lung fields from apices to costo-phrenic angles should be clearly demonstrated.
2. No rotation. Rotation on a PA chest radiograph can be determined by examining both sternal ends of the clavicles for a symmetric appearance in relationship to the spine. On a true PA chest without any rotation, both the right and left sternal ends of the clavicle will be the same distance from the center line of the spine. The direction of rotation can be determined by which sternal end of the clavicle is closest to the spine.
3. Trachea is visible in midline.

4. Scapula projected outside the lung fields.
5. Ten posterior ribs are visible above the diaphragm.
6. There is a sharp outline of the heart and diaphragm.
7. A faint shadow of the ribs and superior thoracic vertebrae is visible through the heart shadow.
8. Lung markings are visible from the hilum to the periphery of the lung.(102)

ANNEXURE 5 – METHODOLOGY OF ANTERO-POSTERIOR RADIOGRAPHY

METHOD OF ANTERO – POSTERIOR CHEST RADIOGRAPH

They are generally of poorer quality than a postero-anterior (PA) radiograph or recumbent films made in the radiology department. Hence, it is preferable to obtain a film in the radiology department unless the patient cannot be moved without hazard. These are the general principles that were followed to take an antero-posterior chest radiograph.

Patient position considerations

The patient was instructed to lie supine or upright, with the back against the grid. If possible, the head end of the cart was raised, as the semi-erect position improves the anatomical details.

In a portable, an upright portable film is preferable to a supine film. The patient's position and the distance from the x-ray tube to the film should be recorded on the film cassette.

Position of chest

1. The mid-sagittal plane of the chest was to be in the center of the cassette.

2. If the patient's condition allowed, the patient was asked to relax the shoulders and place hands on hips (to move the scapula away from the lung fields).
3. If the patient cooperated, the patient was instructed to take a deep breath and then hold it to fully aerate the lungs. The patient is then asked to take a second deep breath. The exposure was made at the end of the second full inspiration to ensure maximum expansion of the lungs.

Film holder placement

For AP chest radiographs, the cassette film holder or image receptor (IR) was placed crosswise, using a 14 x 17-inch (35 x 43-cm) IR. The cassette was adjusted so that the upper border is approximately 1 1/2 to 2 inches (3.8-5 cm) above the shoulders.

Central ray

The central ray (CR) was set perpendicular to the long axis of the sternum and the center of the cassette. The jugular notch was the recommended landmark for the location of the CR for AP chest radiographs. The notch was used to locate the center of the lung fields at the T7 level (mid-thorax).

The T7 level in an average adult is 3-4 inches (8-10 cm) below the jugular notch.

Evaluation criteria for a good AP projection

1. The entire lung fields from apices to the costo-phrenic angles should be clearly demonstrated.
2. No rotation - the sternal ends of the clavicle should be at the same distance from the center line of the spine. However, in portable radiographs it is sometimes not achievable due to the condition of the patient.
3. The trachea should be visible in the midline.
4. The scapulae are usually projected in the lung fields.
5. Full inspiration is usually not achievable in ill patients; generally, only eight or nine ribs are visualized above the diaphragm.
6. Three posterior ribs should be seen above clavicles if the CR angle is correct.
7. Clavicles are projected higher and the ribs assume a more horizontal position.
8. The heart and great vessels appear magnified.
9. A faint image of the ribs and thoracic vertebrae should be visible through the heart shadow.
10. The outline of the heart and diaphragm should be sharp.(103)

ANNEXURE 6—CLINICAL RESEARCH FORM

LUNG ULTRASOUND IN MEDICAL WARDS

To be filled by Principal Investigator

Serial Number :Name :

Hospital Number :Age :

Gender : Male / Female

Occupation :

Ventilated : Yes / No

Chest Tube : Yes / No

Position of patient : Upright / Supine / Right lateral / Left lateral

CXR done on -

Lung USG done on—

Time -

Time –

Co – morbidities– Diabetes / HTN / HIV / Bronchial Asthma / Hypothyroidism / Prev TB

History –Cough / Breathlessness / Expectoration / Chest pain (Area -) /
Hemoptysis / Fever spike / Pedal edema / Elevated JVP/ Smoker / Alcoholic

Duration of history -

Clinical Examination –

Areas	Right		Left	
Infra-clavicular	Normal	Bronchial BS	Normal	Bronchial BS
	Decreased BS	Pleural rub	Decreased BS	Pleural rub
	Absent BS	Others -	Absent BS	Others -
	Crepitations	Wheeze	Crepitations	Wheeze
Mammary	Normal	Bronchial BS	Normal	Bronchial BS
	Decreased BS	Pleural rub	Decreased BS	Pleural rub
	Absent BS	Others -	Absent BS	Others -
	Crepitations	Wheeze	Crepitations	Wheeze
Axillary	Normal	Bronchial BS	Normal	Bronchial BS
	Decreased BS	Pleural rub	Decreased BS	Pleural rub
	Absent BS	Others -	Absent BS	Others -
	Crepitations	Wheeze	Crepitations	Wheeze
Infra-axillary	Normal	Bronchial BS	Normal	Bronchial BS

	Decreased BS	Pleural rub	Decreased BS	Pleural rub
	Absent BS	Others -	Absent BS	Others -
	Crepitations	Wheeze	Crepitations	Wheeze
Supra scapular	Normal	Bronchial BS	Normal	Bronchial BS
	Decreased BS	Pleural rub	Decreased BS	Pleural rub
	Absent BS	Others -	Absent BS	Others -
	Crepitations	Wheeze	Crepitations	Wheeze
Inter scapular	Normal	Bronchial BS	Normal	Bronchial BS
	Decreased BS	Pleural rub	Decreased BS	Pleural rub
	Absent BS	Others -	Absent BS	Others -
	Crepitations	Wheeze	Crepitations	Wheeze
Infra scapular	Normal	Bronchial BS	Normal	Bronchial BS
	Decreased BS	Pleural rub	Decreased BS	Pleural rub
	Absent BS	Others -	Absent BS	Others -
	Crepitations	Wheeze	Crepitations	Wheeze

USG Screening –

7 points	Right		Left	
Infra-clavicular	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others
Mammary	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others
Axillary	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others

PLAP	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others
Supra scapular	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others
Inter scapular	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others
Infra scapular	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others

Other comments –

Final Diagnosis –

Outcome – Alive / Dead / DAMA

Time taken for CXR -

Time taken for USG -

LUNG ULTRASOUND IN MEDICAL WARDS

To be filled by Primary Treating Physician

Serial Number :

Name :

Hospital Number :

When was CXR ordered:

When was CXR done :

Time Lag -

CXR Interpretation –

Zones	Right		Left	
Upper	Normal	Miliary mottling	Normal	Miliary mottling
	Effusion	Hilar LN	Effusion	Hilar LN
	Consolidation	Mediatinal widening	Consolidation	Mediatinal widening
	Interstitial dis	Pneumothorax	Interstitial dis	Pneumothorax
	Mass	Others	Mass	Others
Middle	Normal	Miliary mottling	Normal	Miliary mottling
	Effusion	Hilar LN	Effusion	Hilar LN
	Consolidation	Mediatinal widening	Consolidation	Mediatinal widening
	Interstitial dis	Pneumothorax	Interstitial dis	Pneumothorax
	Mass	Others	Mass	Others
Lower	Normal	Miliary mottling	Normal	Miliary mottling
	Effusion	Hilar LN	Effusion	Hilar LN
	Consolidation	Mediatinal widening	Consolidation	Mediatinal widening
	Interstitial dis	Pneumothorax	Interstitial dis	Pneumothorax
	Mass	Others	Mass	Others

Other comments –

Final Radiological Diagnosis –

LUNG ULTRASOUND IN MEDICAL WARDS

To be filled by Radiologist

Serial Number :

Date :

Name :

Age :

Hospital Number :

Gender : Male / Female

History and Examination - Cough / Breathlessness / Expectoration / Chest pain () / Hemoptysis / Fever spike / Decreased BS / Crepitations / Bronchial BS / Pleural rub

Area-

CXR Interpretation –

Zones	Right		Left	
Upper	Normal	Miliary mottling	Normal	Miliary mottling
	Effusion	Hilar LN	Effusion	Hilar LN
	Consolidation	Mediatinal widening	Consolidation	Mediatinal widening
	Interstitial dis	Pneumothorax	Interstitial dis	Pneumothorax
	Mass	Others	Mass	Others
Middle	Normal	Miliary mottling	Normal	Miliary mottling
	Effusion	Hilar LN	Effusion	Hilar LN
	Consolidation	Mediatinal widening	Consolidation	Mediatinal widening
	Interstitial dis	Pneumothorax	Interstitial dis	Pneumothorax
	Mass	Others	Mass	Others
Lower	Normal	Miliary mottling	Normal	Miliary mottling
	Effusion	Hilar LN	Effusion	Hilar LN
	Consolidation	Mediatinal widening	Consolidation	Mediatinal widening
	Interstitial dis	Pneumothorax	Interstitial dis	Pneumothorax
	Mass	Others	Mass	Others

Other comments – Final Diagnosis –

LUNG ULTRASOUND IN MEDICAL WARDS

To be filled by Expert in Lung Ultrasonogram

Serial Number : Date :

Name : Age :

Hospital Number : Gender : Male / Female

History and Examination - Cough / Breathlessness / Expectoration / Chest pain () / Hemoptysis / Fever spike / Decreased BS / Crepitations / Bronchial BS / Pleural rub

Area –

USG Interpretation –

7 points	Right		Left	
Infra-clavicular	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others
Mammary	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others
Axillary	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others
PLAP	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others
Supra scapular	Normal	Consolidation	Normal	Consolidation
	No lung sliding	Sub pleural cons	No lung sliding	Sub pleural cons
	B lines <3	Effusion	B lines <3	Effusion
	B lines >3	Others	B lines >3	Others
Inter scapular	Normal	Consolidation	Normal	Consolidation

	No lung sliding B lines <3 B lines >3	Sub pleural cons Effusion Others	No lung sliding B lines <3 B lines >3	Sub pleural cons Effusion Others
Infra scapular	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others	Normal No lung sliding B lines <3 B lines >3	Consolidation Sub pleural cons Effusion Others

Other comments –

Final Diagnosis –

LUNG ULTRASOUND IN MEDICAL WARDS

Composite reference standard

Serial Number :

Name :Date :

Hospital Number : Age : Gender : Male /
Female

Co-morbidities– Diabetes / HTN / HIV / Bronchial asthma / Hypothyroidism

History and clinical examination–Cough / Breathlessness / Exp/ Chest pain (Area -
) / Hemoptysis / Fever spike / Pedal edema / Elevated JVP / Decreased BS / Fine
Crepitations / Coarse crepitations / Bronchial BS / Pleural rub/ Wheeze

Area -

Duration of History -

Investigations (At presentation) -

Haemoglobin						CXR	
TC/DC		N -	L -	E -	BF -		
Platelets							
Pro-calcitonin						USG	
Sputum AFB							
Xpert TB PCR							
ABG	pH					Other imaging (CT)	
	pO ₂						
	pCO ₂						
	HCO ₃						
	Lactate						
	BE						
Sputum culture						ECHO	
Blood cultures						MGIT/ LJ Culture	

Pleural fluid analysis	TC					pH	
	DC	N -	L-	Rbc -	BF -	PCV	
	Prot/ser					ADA	
	LDH/ ser					Xpert	
	Glucose					Others	

Others –

Final Respiratory Diagnosis –

ANNEXURE 7: ETHICS COMMITTEE APPROVAL



OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho MS Ortho DNB Ortho.
Chairperson, Research Committee & Principal

Dr. Biju George, MBBS., MD., DM
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

May 23, 2016

Dr. Manisha Arthur,
PG Registrar
Department of General Medicine-2,
Christian Medical College,
Vellore 632 004.

Sub: **Fluid Research Funding: New Proposal**
Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR).
Dr. Manisha Arthur (Employment Number: 29484), PG registrar General Medicine (Unit 2), Dr. Thambu David Employment Number: 30008, Medicine, Dr. Kishore Pitchamuthu, Employment number: 28399 Medical Intensive Care unit, Dr. Turaka Vijay Prakash Employment number: 28591 Department of medicine, Dr. Tharani Putta Employment number: 29040, Radiology, Dr. Mohammad Sadiq, Employment number: 29104, Endocrinology, Dr. Anand Zachariah, Employment number: 11791, medicine, Dr. Somasathyendra, Employment number: 28181, medicine unit 3, Dr. Samuel George Hansdak Employment number: 30829, medicine unit 4, Dr. Ramya Employment number: 31571, medicine, Mrs. Reka K Employment number: 32547, Biostatistics

Ref: IRB Min No: 9820 [DIAGNO] dated 07.01.2016

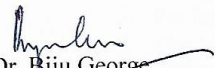
Dear Dr. Manisha Arthur,

I enclose the following documents:-

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,


Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Thambu David, Professor Dept. of Medicine 2, CMC

1 of 4



**OFFICE OF RESEARCH
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CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

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Ref: IRB Min No: 9820 [DIAGNO] dated 07.01.2016

Dear Dr. Manisha Arthur,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR).." on January 07th 2016.

The Committee reviewed the following documents:

1. IRB Application format
2. Patient Information Sheet and Informed Consent Form (English, Tamil, Hindi, Telugu)
3. Proforma
4. Cvs of Drs. Manisha Arthur., Thambu David, Kishore Pitchamuthu, Turaka Vijay Prakash, Tharani Putta, Mohammad Sadiq, Anand Zachariah, . Samuel George Hansdak, Ramya, Mrs. Reka K
5. No. of documents 1- 4

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OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
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Chairperson, Research Committee & Principal

Dr. Biju George, MBBS., MD., DM
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on January 07th 2016 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Affiliation
Dr. Nihal Thomas	MD, MNAMS, DNB(Endo), FRACP (Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson(Research Chairperson), Member Secretary (Ethics Committee), IRB. CMC, Vellore	Internal, Clinician
Dr. RV. Shaji		Professor, Heamatology, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. Visalakshi. J	MPH, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Rajesh Kannangai	MD, PhD.	Professor, Clinical Virology, CMC, Vellore	Internal, Clinician
Dr. Niranjana Thomas	DCH, MD, DNB (Paediatrics)	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. B. J. Prashantham	MA(Counseling Psychol MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Cent Vellore	External, Social Scientist
Dr. Ratna Prabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist

IRB Min No: 9820 [DIAGNO] dated 07.01.2016

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**OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

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Chairperson, Research Committee & Principal

Dr. Biju George, MBBS., MD., DM
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Anand Zachariah	MBBS, PhD	Professor, Medicine, CMC, Vellore	Internal, Clinician
Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro) Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Simon Pavamani	MBBS, MD	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
Dr. Inian Samarasam	MS, FRCS, FRACS	Professor, Surgery, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MD, DNB(Endo), Phd(Endo)	Professor, Endocrinology, CMC, Vellore	Internal, Clinician

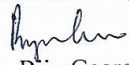
We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Bedside Lung Ultrasonography In A General Medical Ward – Comparison With Chest Radiography (BLUR)." on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in)

Fluid Grant Allocation:

A sum of 1,00,000/- INR (Rupees One Lakh Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an 1st Installment. The rest of the 50,000/- INR (Rupees Fifty Thousand only) each will be released at the end of the first year as 2 nd Installment

Yours sincerely


Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min No: 9820 [DIAGNO] dated 07.01.2016

4 of 4

ANNEXURE 8: FUNDING APPROVAL

From: Accounts Projects
Sent: Monday, August 22, 2016 1:44 PM
To: Thambu David
Cc: Principal's Office - Research; med2
Subject:

CHRISTIAN MEDICAL COLLEGE
Office of the Treasurer

Date: 22-08-2016

Dear Dr. Manisha Arthur

As requested by the Vice-Principal (Research) with the IRB Minute No. 9820 a new Fluid research account opened for your Project, the account no are as follows:-

22 Y 953

This is for your information

Thanking you.

Yours sincerely

P. BASKARAN
Sr. Manager (F&A)
Accounts

ANNEXURE 9 – STARD CHECKLIST

Section & Topic	No	Item
TITLE OR ABSTRACT		
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)
ABSTRACT		
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)
INTRODUCTION		
	3	Scientific and clinical background, including the intended use and clinical role of the index test
	4	Study objectives and hypotheses
METHODS		
<i>Study design</i>	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)
<i>Participants</i>	6	Eligibility criteria
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)
	8	Where and when potentially eligible participants were identified (setting, location and dates)
	9	Whether participants formed a consecutive, random or convenience series
<i>Test methods</i>	10a	Index test, in sufficient detail to allow replication
	10b	Reference standard, in sufficient detail to allow replication
	11	Rationale for choosing the reference standard (if alternatives exist)
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test
	13b	Whether clinical information and index test results were available to the assessors of the reference standard
<i>Analysis</i>	14	Methods for estimating or comparing measures of diagnostic accuracy
	15	How indeterminate index test or reference standard results were handled
	16	How missing data on the index test and reference standard were handled
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory
	18	Intended sample size and how it was determined
RESULTS		
<i>Participants</i>	19	Flow of participants, using a diagram
	20	Baseline demographic and clinical characteristics of participants
	21a	Distribution of severity of disease in those with the target condition
	21b	Distribution of alternative diagnoses in those without the target condition
	22	Time interval and any clinical interventions between index test and reference standard
<i>Test results</i>	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)
	25	Any adverse events from performing the index test or the reference standard
DISCUSSION		
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability
	27	Implications for practice, including the intended use and clinical role of the index test
OTHER INFORMATION		
	28	Registration number and name of registry
	29	Where the full study protocol can be accessed
	30	Sources of funding and other support; role of funders

ANNEXURE 10 – DATA SET

IDNO	NAME	HOSPNO	AGE	SEX	LUS	EFF	CONS	PTX	PED	ARDS	RCKR	RXEFF	RXCONS	RXMASS	RXMIL	RXHIL	RXMEDI	RPED	RARDS
1	PADMANABH MAHATO	511745G	79	1	1	1	5	0	0	0	1	1	3	0	0	1	1	0	0
2	NURUL AMIN	625769G	42	1	1	0	3	0	0	1	1	1	2	0	0	0	0	0	0
3	VISWANATHAN	514788G	70	1	0						0								
4	MONI KUMARI	514792G	28	2	1	0	6	0	0	0	0								
5	SABIRA	685045B	56	2	1	0	0	0	0	0	0								
6	CHIDAMBARAM	944976B	63	1	1	1	5	0	1	0	1	1	5	0	0	0	0	0	0
7	AZZEZULAH	222925F	51	1	1	0	6	0	0	0	0								
8	KASI	523223A	77	1	1	0	6	0	1	0	0								
9	SHAPNA DAS	514980G	37	2	1	0	4	0	1	0	1	0	9	0	0	0	0	0	0
10	SANKAR	514983G	30	1	1	0	6	0	0	0	0								
11	VALLI	514963G	42	2	1	1	0	0	0	0	1	1		0	0	0	1	0	0
12	GOVINDASAMY	922607F	67	1	1	3	5	0	0	0	1	3	0	0	0	0	0	0	0
13	HIMALAY DAS	514041G	18	1	0						0								
14	DHANABAKIYAMMAL	512764G	70	2	1	1	7	0	1	0	1	3	7	0	0	0	0	0	0
15	RAMAMOORTHY	053676C	66	1	0						1	0	4	0	0	0	0	0	0
16	INIYAN	516051G	40	1	1	0	6	0	0	0	0								
17	SRINIVASAN	562262A	76	1	0						0								
18	RAVIKUMAR	480285D	56	1	1	1	5	0	0	0	1	1	5	0	0	0	0	0	0
19	NARASIMHA	514343G	76	1	0						0								
20	KUMAR	516473G	55	1	1	3	7	0	0	1	1	3	7	0	0	0	0	0	0
21	ANBUKARASAN	514861G	47	1	1	1	0	0	0	0	1	3	0	0	0	0	0	0	0
22	BIBHAS	640562G	50	1	0						0								
23	ULAGANATHAN	975732F	41	1	1	0	0	0	0	1	1	0	0	3	0	0	0	0	1
24	ARUNA	400790G	40	2	1	0	9	0	0	1	1	0	6	0	0	0	0	0	0
25	KALAISELVI	868185D	30	2	0						0								
26	MICHEL	514505G	23	1	1	0	6	0	0	0	1	0	7	0	0	0	0	0	0
27	GAUTAM	963810C	41	1	1	0	6	0	0	0	1	0	0	0	0	1	0	0	0
28	RUBY	516708G	45	2	1	0	0	0	0	1	1	1	3	0	0	0	0	0	0
29	PRAVEENA	644581G	38	2	1	0	3	0	0	0	1	0	2	0	0	0	0	0	0
30	BALAMMAL	359604F	64	2	0						0								
31	GOWRIAMMAL	514857G	78	2	1	0	6	0	0	0	0								
32	KALAISELVAN	516723G	26	1	0						0								
33	LALU PRASAD	638800G	47	1	1	1	0	0	1	0	1	1	0	0	0	0	0	1	0
34	VELU	516011G	67	1	0	0	6	0	0	0	0								
35	VELLIAMAL	516710G	60	2	1	0	1	0	0	0	1	0	1	0	0	0	0	0	0
36	BASHA	336087D	68	1	1	1	3	0	0	0	1	1	3	0	0	0	0	0	0
37	JANI BASHA	518419G	57	1	0						0								
38	BATHALA	518339G	37	1	1	0	7	0	1	0	1	1	3	0	0	0	0	1	0
39	GOBINDA	516832G	32	1	1	0	5	0	0	0	1	3	0	0	0	0	0	0	0
40	IRUDAYARAJ	642578G	70	1	1	3	0	0	0	0	1	3	0	0	0	0	0	0	0
41	SRINIVASAN	518323G	18	1	0						0								
42	PYAPILI	518226G	30	2	1	3	7	0	0	1	1	3	7	0	0	0	0	0	1
43	DEVAKI	380808C	72	2	0						0								

44	MURUGESAN	916086C	70	1	0								0						
45	JAYARAJU	636112G	80	1	0								0						
46	SUGUMAR	520044G	55	1	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0
47	BHASKAR	514924G	52	1	1	1	7	0	0	0	1	1	0	0	0	0	0	0	0
48	RAMA MURTHY	520267G	57	1	0						1	0	0	0	0	0	0	0	0
49	MANI	520212G	69	1	0						0								
50	BASKAR	521230F	55	1	0						1	2	7	0	0	0	0	1	0
51	SWATI	520383G	30	2	0						1	3	0	0	0	0	0	0	0
52	SALOMI	452204F	59	2	0						0								
53	PARAMESHWARI	510143G	76	2	1	0	3	0	0	0	1	3	0	0	0	0	0	0	0
54	SHIRIN	890000B	48	2	0						0								
55	TANJILA	516842G	20	2	0						0								
56	VENKATESAN	520552G	47	1	0						0								
57	VENKATESAN	105389G	59	1	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0
58	MASTHAN	521321F	60	2	1	0	0	0	0	1	1	1	3	0	0	0	0	0	0
59	DESHBANDHU	649169G	36	1	0						0								
60	GOPI	520989G	30	1	1	0	0	0	1	0	1	1	5	0	0	0	0	0	0
61	GOUTAM	641414g	49	1	1	3	0	0	0	0	1	1	5	0	0	0	0	0	0
62	BADSHA	662469G	28	1	0						0								
63	BOOPALAN	521028G	54	1	1	2	6	0	0	0	1	0	3	0	0	0	0	0	0
64	THARUN	616014G	61	1	1	0	3	0	0	0	1	0	7	0	0	0	0	0	0
65	SARASWATHI	521280G	28	2	1	3	7	0	0	1	1	3	7	0	0	0	0	0	1
66	MANGAILAKSHMI	521372G	75	2	0						1	3	0	0	0	0	0	0	0
67	MALLA REDDY	521283G	32	1	1	0	0	0	0	1	1	1	0	0	0	0	0	0	0
68	SAMPATH	521454G	40	1	1	0	3	0	0	0	1	0	8	0	0	0	0	0	0
69	SAMIKANNU	521425G	68	1	1	2	6	0	0	0	1	0	6	0	0	0	0	0	0
70	VANAROJA	521655G	65	2	1	3	7	0	0	0	1	1	3	0	0	0	0	0	0
71	VIJAYA KUMAR	458838D	49	1	1	0	0	0	0	1	1	0	6	0	0	0	0	0	0
72	NITHIYA	521706G	17	2	0						0								
73	APPALA	671086G	65	1	1	0	0	0	1	0	1	0	0	0	0	0	0	0	1
74	SUNDARESAN	995928F	47	1	0						1	0	0	0	0	0	0	1	0
75	GOVINDAMMAL	505949G	55	2	0						0								
76	PACHIYAPAN	108046G	56	1	1	0	0	0	1	0	0								
77	KANAKARAYAN	120808C	66	1	0						0								
78	CHINNADURAU	521866G	31	1	1	3	7	0	0	0	1	3	5	0	0	0	0	0	0
79	MURUGAN	523333G	33	1	0						1	0	7	0	0	0	0	0	0
80	AARUMUGAM	523462G	46	1	1	0	0	0	1	0	1	0	0	0	0	0	0	1	0
81	VIMALA	523405G	29	2	1	0	0	0	1	0	1	0	0	0	0	0	0	1	0
82	SAROJINI	293994D	77	2	1	3	6	0	1	0	1	3	0	0	0	0	0	1	0
83	ROSY	783819F	36	1	0						0								
84	RAO	524013G	84	1	1	3	7	0	0	0	0								
85	AMULU	518381G	38	2	0						0								
86	DEVARAJ	523968G	42	1	1	1	0	0	0	1	1	0	7	0	0	0	0	0	0
87	VASU	523834G	52	1	1	3	7	0	1	0	1	3	0	0	0	0	0	1	0
88	MD FAIZUL	524102G	56	1	1	1	0	0	0	0	0								
89	RAJESHWARI	523886G	40	2	1	1	5	0	0	0	1	1	5	0	0	0	0	0	0
90	NURUDDIN	524110G	32	1	0						1	0	0	0	0	0	0	0	1

91	KHAMURINISSA	524481G	60	2	1	3	7	0	0	0	1	3	0	0	0	0	0	1	0
92	SAROJAMMAL	524527G	75	2	1	2	0	0	0	0	0								
93	SARANYA	524533G	25	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0	0
94	MANOHARI	524524G	72	2	0						0								
95	VASANTHAMMAL	524229G	56	2	0						0								
96	RAMACHANDRA	524580G	58	1	1	1	7	0	1	0	1	0	0	0	0	0	0	1	0
97	SREENIVASALU	524419G	62	1	1	3	0	0	0	0	1	3	7	0	0	0	0	0	0
98	PYARAJAN	368172D	69	1	1	1	6	0	0	0	1	0	6	0	0	0	0	0	0
99	RAVICHANDRAN	952127F	49	1	0						0								
100	MUTHU	704916D	82	1	1	2	0	0	0	0	0								
101	RAMACHANDIRAN	526075G	33	1	1	0	7	0	0	0	1	0	0	0	0	0	0	0	1
102	SURESH	526120G	62	1	0						0								
103	PATHBANABAN	527368G	61	1	0						0								
104	SIVASANKARAN	275444F	72	1	1	3	0	0	0	0	1	3	0	0	0	0	0	0	0
105	KRISHNA	530146G	63	1	1	3	7	0	0	0	1	0	0	0	0	0	0	1	0
106	ANANDHAN	526147G	40	1	1	0	2	0	0	0	1	1	2	0	0	0	0	0	0
107	PARASAKTHI	532087G	55	2	1	3	6	0	0	0	1	2	7	0	0	0	0	0	0
108	REGINA	532103G	49	2	0	0	0	0	0		0								
109	VANITHA	532101G	66	2	0						0								
110	PRAVIN	407307B	77	1	0						0								
111	VASANTHA	532076G	66	2	1	0	0	0	0	1	0								
112	MUDE	739226G	29	1	0						0								
113	RANI	193395F	46	2	1	3	7	0	1	0	1	3	7	0	0	0	0	1	0
114	KHURSHIDA	534218G	35	2	0						0								
115	RAJASEKHAR	534233G	24	1	1	2	0	0	0	1	0								
116	GAYATHRI	668200F	36	2	1	0	0	0	0	1	1	3	7	0	0	0	0	0	0
117	DHARMALINGAM	701355A	79	1	0						0								
118	EZHILARASI	750168G	19	2	1	0	3	0	0	0	1	1	3	0	0	0	0	0	0
119	KANCHAMAALAI	536496G	32	2	1	0	1	0	0	0	1	0	1	0	0	0	0	0	0
120	ANUSIYA	534490G	19	2	1	0	0	0	1	0	1	0	0	0	0	0	0	1	0
121	GOPI	064024F	72	1	0						0								
122	JAYANATHAN	140611C	36	1	1	0	0	0	0	1	1	0	1	0	0	0	0	0	1
123	ASMA	461656D	55	2	0						0								
124	KAMALATCHI	547024A	44	2	0						0								
125	SUSILA	536848G	60	2	1	0	0	0	0	1	1	0	0	0	0	0	0	0	1
126	SITARASU	536833G	22	1	1	2	6	0	0	0	1	3	0	0	0	0	0	0	0
127	LAKSHMI	751989G	49	2	1	0	7	0	1	0	1	3	2	0	0	0	0	0	0
128	BISWANATH	684333G	61	1	1	1	5	0	0	0	1	1	0	2	0	0	0	0	0
129	VASANTHA	081337D	47	2	1	0	0	0	1	0	1	0	0	0	0	0	0	1	0
130	KANNU	539396G	70	1	0						0								
131	SHANKAR	539364G	80	1	1	0	3	0	0	0	0								
132	SHANMUGAM	496899B	65	1	0						0								
133	KALAVATHY	539492G	40	2	0						0								
134	BIMAL	746187G	25	1	0						0								
135	RAVI	539643G	46	1	1	3	0	0	1	0	1	3	0	0	0	0	0	0	0
136	RAJENDRAN	539687G	63	1	0						0								
137	SUNIL	377922G	35	1	1	2	0	0	0	0	1	2	0	0	0	0	0	0	0

138	JAMUNABAI	539680G	63	2	0						0								
139	KUMAR	539707G	37	1	1	0	6	0	0	1	1	0	0	0	0	0	0	0	1
140	SHANTHA	540581G	61	2	1	1	3	0	0	0	1	1	0	0	0	0	0	0	0
141	SATISH	539299G	33	1	0						0								
142	RAJENDRAN	884512F	58	1	1	3	7	0	1	0	1	1	0	0	0	0	0	0	0
143	EZHUMALAI	540556G	25	1	0						0								
144	SUKUMAR	540651G	60	1	1	0	3	0	0	0	1	1	0	0	0	0	0	0	0
145	ANNAMALAI	658304G	68	1	0						1	0	1	0	0	0	0	0	0
146	MANOGANDHI	275510G	58	2	1	1	0	0	1	0	0								
147	ANIL	765427G	54	1	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0
148	MALARKODI	191956C	60	2	1	0	3	0	0	0	1	1	5	0	0	0	0	0	0
149	PUSHPARANI	542993G	71	2	0						0								
150	RANGANATHAN	932239F	60	1	1	0	2	0	0	0	1	1	5	0	0	0	0	0	0
151	MUMTAJ	542970G	70	2	0						1	0	5	0	0	0	0	0	0
152	MANIVANNAN	543000G	50	1	1	0	0	0	1	0	0								
153	DHANARAJ	543006G	75	1	0						0								
154	DAVID	544757G	55	1	1	2	6	0	0	0	1	2	6	0	0	0	0	0	0
155	RAMAKRISHNA	518952F	60	1	0						1	0	7	0	0	0	0	0	0
156	EDWIN	878521B	78	1	0						0								
157	ABDUL	546071G	76	1	1	0	0	0	1	0	0								
158	JOTHI	546090G	54	2	1	2	6	0	0	0	1	0	6	0	0	0	0	0	0
159	PITCHIAMMAL	791864G	51	2	1	2	6	0	0	0	1	2	0	0	0	0	0	0	0
160	SELVA MARY	640131D	42	2	1	0	7	0	0	0	1	0	6	0	0	0	1	0	0
161	KAVITHA	415532G	41	2	1	0	6	0	0	0	1	0	6	0	0	0	0	0	0
162	SELVI	903103C	47	2	1	3	3	0	0	0	1	3	0	0	0	0	0	0	0
163	KAVIPRIYA	546215G	22	2	1	3	7	0	0	0	1	3	0	0	0	0	0	0	0
164	NISHIKANTH	795051G	24	1	1	0	7	0	0	0	1	3	0	0	0	0	0	0	0
165	BADHAN	738334G	51	1	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0
166	NAGARAJAN	546551G	59	1	1	0	1	0	0	0	1	0	1	0	0	0	0	0	0
167	KRISNA REDDY	546570G	51	1	1	3	3	0	0	0	1	3	0	0	0	0	0	1	0
168	KHALIQUE	546301G	52	1	1	3	0	0	0	0	1	3	0	0	0	0	0	0	0
169	POONGAVANAM	875670D	59	2	1	3	3	0	0	1	0								
170	NAGAMMAL	546494G	64	2	1	3	3	0	0	0	1	3	0	0	0	0	0	1	0
171	AMBATI	546627G	19	2	1	2	7	0	0	0	1	0	7	0	1	0	0	0	0
172	JAMUNA	546596G	59	2	1	0	7	0	0	0	1	0	0	1	7	0	0	0	0
173	SANGITA	778167G	18	2	1	0	7	0	0	0	1	0	7	0	1	0	0	0	0
174	GANAPATHY	374622	71	1	0						0								
175	SAROJA	072614A	71	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0	0
176	ASHOKAN	289610B	53	1	1	0	6	0	0	0	1	0	1	0	0	0	0	0	0
177	JEEVARATHINAM	546827G	69	1	0						1	1	0	0	0	0	0	0	0
178	KUPPAN	546805G	50	1	1	1	6	0	0	0	1	1	0	0	0	0	0	0	0
179	WAKIL	546759G	47	1	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0
180	DANAM	546774G	70	1	1	3	0	0	0	0	1	3	0	0	0	0	0	0	0
181	THULASI	547196G	37	2	1	0	3	0	0	0	1	0	2	0	0	0	0	0	0
182	VEENA	180405A	36	2	1	0	0	0	0	1	1	3	7	0	0	0	0	0	0
183	DHANAKALA	547932G	53	2	1	1	3	0	0	0	1	1	7	0	0	0	0	0	0
184	SUBRAMANIAM	527889F	65	1	1	2	0	0	1	0	1	1	0	0	0	0	0	1	0

185	SUBRAMANI	707713D	67	1	1	0	4	0	0	0	1	0	4	0	0	0	0	0
186	AKSHAY	723398C	65	1	1	0	3	0	0	0	1	1	3	0	0	0	0	0
187	LAKSHMI	770565G	51	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0
188	DEVANI	249399F	54	2	0						0							
189	JYOTHI	547951G	52	2	1	0	6	0	0	0	1	2	0	0	0	0	0	0
190	SAKINA	777134G	39	2	1	0	6	0	0	0	0							
191	PONNAMMAL	658309D	72	2	1	0	6	0	0	0	1	2	6	0	0	0	0	0
192	SHANMUGAM	548383G	71	1	0						0							
193	SETTU	970244D	55	1	1	2	6	0	0	0	1	2	6	0	0	0	0	0
194	RAMALAKSHMMA	810680D	67	2	0						0							
195	YUVAKUMAR	404901B	66	1	0						1	3	7	0	0	0	0	0
196	DEVA PRASAD	548549G	55	1	1	0	6	0	0	1	1	3	1	0	0	0	0	0
197	GOPI	828953G	45	1	0						1	0	1	0	0	0	0	0
198	GOKUL	548535G	18	1	0						0							
199	RAJESHWARI	015600C	37	2	1	3	0	0	0	0	1	2	0	0	0	0	0	0
200	REKHA	448321A	33	2	0						1	0	0	0	0	0	0	0
201	PARTHEEBAN	545428G	37	1	0						0							
202	SIDDHANTH	548507G	19	1	1	3	3	0	0	0	1	3	7	0	0	0	0	0
203	KASTHURI	200367G	57	2	1	0	5	0	0	0	1	3	5	0	0	0	0	0
204	KADAR BASHA	558656G	34	1	0						1	0	2	0	0	0	0	0
205	PRAKASH	861977G	42	1	1	3	0	0	0	0	0							
206	MOHANA	847410G	32	2	0						0							
207	NEELES	558391G	16	1	1	0	3	0	0	0	1	1	3	0	0	0	0	0
208	JOSEPH	558706G	64	1	1	0	0	0	1	0	0							
209	PACHIYAPPAN	558743G	65	1	0						0							
210	SHEULE	867853G	55	2	0						0							
211	KASIAMMAL	527851G	70	2	1	0	0	0	0	0	0							
212	PAPPUGIRI	558916G	28	2	0						0							
213	SANGEETHA	558750G	28	2	0						0							
214	KATHAVARAYAN	558778G	24	1	1	3	3	0	0	0	1	1	6	0	0	0	0	0
215	NEMAI	559383G	45	1	1	1	0	0	0	0	1	1	0	1	0	0	0	0
216	KOTHANAYAKI	624054	60	2	0						1	0	0	0	0	0	0	0
217	SHILA	559347G	51	2	1	1	0	0	1	0	0							
218	MALAY	559797G	24	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0
219	VIMAL	559811G	60	1	1	3	0	0	0	0	0							
220	DHANUSH	532962G	19	1	1	2	0	0	0	0	1	2	0	0	0	0	0	0
221	ZEERA	559867G	35	2	1	0	3	0	0	0	1	3	7	0	0	0	0	0
222	ANBARASAN	213911F	16	1	1	1	3	0	0	0	1	1	2	0	0	0	0	0
223	GOVINDASWAMY	559888G	69	1	0						1	1	0	0	0	1	0	0
224	GOWTHAMI	559777G	65	2	1	3	0	0	0	0	0							
225	ANWARUL	870586G	48	1	0						0							
226	HARADHAN	864580G	45	1	1	3	0	0	0	0	1	3	0	0	0	0	0	0
227	ARUMUGAM	559991G	35	1	1	2	6	0	0	0	1	1	7	0	0	0	0	0
228	KHURSHAD	490824F	58	2	0						0							
229	VIMAL	559340G	18	1	0						0							
230	KANNAN	561038G	57	1	0						0							
231	CHITRA	408598G	26	2	0						0							

232	SHEIKH	561186G	67	2	1	0	3	0	0	0	1	2	0	0	0	0	0	0
233	RAHAMATH	561245G	75	2	0	0	0	0	0	0	1	0	6	0	0	0	0	0
234	PARAMESHWARI	561255G	45	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0
235	ELUMALAI	561242G	70	1	0						0							
236	ADINARAYANA	561298G	41	1	1	1	3	0	0	0	1	1	5	0	0	0	0	0
237	GEETHA	561929G	39	2	0						0							
238	PUNITHAMMAL	889153D	79	2	1	3	0	0	1	0	1	3	0	0	0	0	0	1
239	SAROJA	505577B	80	2	0						0							
240	SUREKHA	561960G	36	2	0						0							
241	VENKATACHALAN	547620G	40	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0
242	KALA	768494D	51	2	1	0	6	0	0	0	1	3	6	0	0	0	0	0
243	VIMALA	562212G	37	2	0						0							
244	SRIDEVI	916753C	36	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0
245	ASHRAF	562178G	64	2	0						0							
246	FAREEDA	106654G	53	2	1	0	0	0	0	0	1	2	4	0	0	0	0	0
247	PUNITHA	562928G	40	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0
248	ASHOK KUMAR	562989G	56	1	1	2	0	0	0	0	1	3	0	0	0	0	0	0
249	ARCHANA	564127G	32	2	1	2	0	0	0	0	1	2	6	0	0	0	0	0
250	SELVI	276897D	43	2	0						1	0	0	0	0	0	0	1
251	SHADA	564184G	56	2	1	1	0	0	0	0	0							
252	ADURI	564803G	30	1	1	0	6	0	0	0	0							
253	KRISHNAN	564806G	80	1	0						1	3	0	0	0	0	0	1
254	DEVARAJ	564793G	55	1	0						0							
255	JYOTSNA	566023G	42	2	1	0	3	0	0	0	1	1	3	0	0	0	0	0
256	CHITTMMA	547460G	58	2	0						0							
257	REVATHI	566013G	31	2	0						0							
258	SARASWATHI	564996G	30	2	0						0							
259	LAKSHMI	564841G	33	2	0						0							
260	SANGEETHA	564882G	20	2	0						0							
261	KUMARESAN	564881G	25	1	0						0							
262	PARASURMAN	566238G	70	1	1	3	0	0	0	0	0							
263	KUMARASWAMY	627642G	76	1	0						0							
264	ELUMALAI	255216B	31	1	0						0							
265	ANAMIKA	907765G	24	2	0						0							
266	VASANTHA	986773F	21	2	0						0							
267	BALARAMAN	949656F	57	1	1	2	0	0	0	0	0							
268	VENDHAN	521365G	53	1	1	3	3	0	0	0	1	3	2	0	0	0	0	0
269	THULASI	566391G	40	2	1	2	0	0	0	0	0							
270	MOHAN	566351G	35	1	1	3	0	0	0	0	1	3	0	0	0	0	0	0
271	PANJAMIRTHAM	566129G	45	1	1	0	1	0	0	0	1	0	1	1	0	0	0	0
272	KANNAN	084339A	44	1	1	2	0	0	0	0	1	3	0	0	0	0	0	1
273	SHANU	566627G	56	2	1	1	0	0	0	0	1	3	0	0	0	0	0	0
274	RAJANGAM	562540G	58	1	0						1	0	1	0	0	0	0	0
275	MEERA	904529G	43	2	1	2	0	0	0	0	1	2	0	0	0	0	0	0
276	SAJIB	549190G	28	1	1	2	0	0	0	0	1	2	0	0	0	0	0	0
277	HEMACHALAM	168167D	66	1	0						0							
278	MARY	566756G	35	2	1	1	0	0	0	0	0							

279	JAYAMMA	566242G	55	2	1	3	0	0	0	0	1	0	0	0	0	0	0	1	0
280	VARALAKSHMI	144087B	65	2	1	3	0	0	0	0	0								
281	NALAPOTHU	566781G	42	1	0						0								
282	MOSES	561585G	60	1	0						0								
283	SONIYA	566861G	26	2	0						0								
284	MUTHU	566934G	57	1	0						0								
285	SELVI	566881G	51	2	1	2	6	0	0	0	1	0	0	0	1	0	0	0	0
286	GAYATHRI	873446G	29	2	1	3	7	0	1	0	1	0	0	0	0	0	0	1	0
287	PRATHIBA	425949D	31	2	1	1	0	0	0	0	0								
288	MOHAMMAD	566964G	20	1	0						0								
289	ANNAPURNA	566947G	57	2	0						1	1	0	0	0	0	0	0	0
290	RAMAIAH	567662G	67	1	1	3	0	0	1	0	1	3	0	0	0	0	0	0	0
291	NAGAMMA	566824G	60	2	1	2	0	0	0	0	1	2	0	0	0	0	0	0	0
292	GANDIKOTA	567580G	32	2	1	0	2	0	0	0	1	0	5	0	0	0	0	0	0
293	POONKODI	567915G	27	2	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0
294	SURESH	567919G	21	1	1	0	3	0	0	0	1	0	7	0	0	0	0	0	0
295	RUMPA	923131G	35	2	0						0								
296	LAKSHMI	567939G	39	2	0						0								
297	MALLIGA	930036G	50	2	1	3	0	0	1	0	0								
298	VENKATESAN	930106G	19	1	1	3	7	0	0	0	0								
299	KURSHEED	448919C	41	2	1	0	6	0	0	0	1	0	6	0	0	0	0	0	0
300	THIRUPATHY	927712G	49	2	0						0								
301	ALO	916239G	50	2	1	1	1	1	0	0	1	3	0	1	0	0	0	0	0
302	SAMPATH	931074G	57	1	1	3	0	0	1	0	0								
303	RUBY	562632G	33	2	0						0								
304	KANAGARAJ	608096D	57	1	1	2	0	0	0	0	1	2	0	0	0	0	0	0	0
305	PANDIAN	496300B	50	1	1	2	6	0	0	0	1	2	6	0	0	0	0	0	0
306	MAGADEVI	883685F	49	2	0						1	2	0	0	0	0	0	0	0
307	KUMAR	474448F	37	1	0						0	0	0	0	0	0	0	0	0
308	SUBRAMAIAH	930013G	50	1	1	3	0	0	1	0	1	1	0	0	0	0	0	0	0
309	ARUL	931143G	22	2	0						0								
310	JAYANTHI	787124C	43	2	1	3	0	0	0	0	1	3	0	0	0	0	0	0	0
311	GOPAL	931109G	62	1	1	0	0	0	0	1	1	0	7	0	0	0	0	0	0
312	ARATI	930236G	52	2	1	0	0	0	0	0	0								
313	SHEELA	682874D	32	2	1	2	0	0	0	0	1	2	0	0	0	0	0	0	0
314	SONI	870947G	27	2	1	3	3	0	0	0	1	3	0	0	0	0	0	0	0
315	CHANDRAN	932284G	83	1	1	3	0	0	0	0	1	2	0	0	0	0	0	0	0
316	BANDANA	932204G	51	2	1	1	0	0	1	0	1	1	1	0	0	0	0	0	0
317	MAHARAJAN	932224G	65	1	0						1	2	0	0	0	0	0	0	0
318	CHINNASAMY	931193G	68	1	1	2	0	0	0	0	1	2	0	0	0	0	0	0	0
319	HEMANTH	931247G	38	1	0						0								
320	GOVINDARAJ	280190D	59	1	0						0								
321	ANNAMALAI	931286G	51	1	1	3	0	0	0	0	0								